



# The EU REACH Regulation

## CMS Supply Chain Innovation Workshop

WSP Environmental Strategies  
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# WSP Environmental



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staff employed in 60 offices across Europe, North America, Africa, Middle East, Australia and Asia Pacific, with headquarters in London

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# Introduction



- “One of the most complex pieces of legislation to ever come out of Europe”
- REACH – **R**egistration, **E**valuation, **A**uthorisation and Restriction of **C**hemicals Regulation
- Implements the new EU Chemicals Policy
- Represents a radical overhaul of existing chemicals legislation – replaces 40 existing laws controlling chemicals
- Entered into force on June 1<sup>st</sup> 2007
- Presents ambitious challenges for industry and CMS providers
- Will likely result in chemicals disappearing from the supply chain and the need to revise manufacturing processes/reformulate process chemicals.

# How Will REACH Impact Industry?

REACH covers:

- Chemical substances and preparations manufactured in the European Union
- Substances and preparations imported into the European Union
- Articles (products) manufactured and imported into the EU

And potentially impacts:

- Companies with EU operations that consume chemicals
- Companies elsewhere that utilize chemicals from the EU
- Manufacturers of articles to be sold in the EU, regardless of where the articles were manufactured
- Manufacturers of chemicals or preparations sold in the EU
  - Chemical companies
  - Manufacturers who sell reagents used in their products
- The chemical supply chain, including CMS providers

***REACH presents both burdens and opportunities for industry***

# Key Elements and Timetable



- Pre-registration
  - Straightforward procedure
  - To establish database and aid working together in groups
- Registration
  - By manufacturers and importers
  - Submission of data & safety assessments
  - Eventually all chemicals > 1tonne/annum
  - Initially addresses high tonnage and chemicals of high concern
- Evaluation
  - Of the submitted data by the authorities
  - Call for missing / extra data

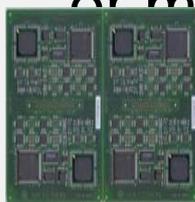
# Key Elements and Timetable



- Authorisation
  - Only for ‘substances of very high concern’
  - Mandatory substitution if safer alternatives exist
  - Continued use on socio-economic or adequately-controlled grounds
  - Time limited
- Exemptions from scope:
  - Substances in regulated products (i.e. medicines, cosmetics)
  - Annex IV substances (i.e. CO<sub>2</sub>, glucose, water)
  - Annex V substances (i.e. manufacturing by-products, certain substances occurring in nature, elemental substances)
  - Polymers (although monomers in polymers in scope if sold separately)
  - Others

# Key Elements and Timetable

- Articles
  - Objects that have been given a special shape, surface or design which determines its function to a greater degree than its chemical composition
  - Examples: computers, printers, circuit boards, cars, pens, etc.
  - As opposed to substances (individual chemicals) and preparations (mixtures of one or more substances)



ification and registration potentially re

- **SVHCs (Substances of Very High Concern) are present > .1% by weight and in amounts over 1**

# Key Elements and Timetable

- Substances of very high concern (SVHCs)
  - Defined in Annex XIV of REACH. Examples include carcinogens, mutagens, persistent and accumulative substances, endocrine disruptors
  - **REACH designed to induce manufacturers of SVHCs to “voluntarily” withdraw these substances from the marketplace, potentially disrupting supply of raw chemicals to industry**
  - Candidate list of SVHCs to be made available by EU by June 2009
  - Reasonable level of confidence regarding which substances will be listed as SVHCs. Some industry lists are being developed.



# Key Elements and Timetable

June 1 <sup>st</sup> 2007	REACH Enters into force
June 1 <sup>st</sup> 2008	Pre-registration begins
Nov 30 <sup>th</sup> 2008	Pre-registration finishes
December 2008	List of Pre-registered substances published
Nov 30 <sup>th</sup> 2010	Registration deadline for >1000t/annum substances 'Substances of Very High Concern'
May 31 <sup>st</sup> 2013	Registration deadline for >100t/annum substances
May 31 <sup>st</sup> 2018	Registration deadline for >1t/annum substances



# Potential Consequences of Inaction

- If substance is unregistered, it will be illegal to put it on the market in the EU
- Risk of disruption to raw material supply chain and manufacturing operations
- May come under increasing scrutiny by customers and non-governmental organizations
- Chemical risks and impact to company liability may not be addressed
- Companies may absorb costs they shouldn't have to bear
- Potential for fines and penalties
- Potential for product liability claims

# What Should Companies be Doing?

- ✓ Understand how REACH applies to the company and business partners
- ✓ Determine registration obligations and pre-register if applicable
- ✓ Determine compliance dates that will drive compliance and implementation
- ✓ Identify business risks including vulnerability of supply chain to disruption
- ✓ Identify gaps in data and processes that will be needed to support REACH compliance
- ✓ Begin communicating up and down the supply chain



# REACH and CMS Providers

First, the bad news:

- CMS providers may have direct REACH registration obligations if they import chemicals into the EU
  - Exception: where the non-EU chemical manufacturer has contracted with an “only representative” and relieved the CMS provider of registration responsibility
- Customers likely to look at REACH as an issue that the CMS provider is being paid to manage
- Costs of REACH will increase costs of chemicals

The good news: CMS providers are positioned to assist their customers with REACH and create value, for example :

- REACH awareness and training for customers
- Providing data needed by customers to comply with REACH
- Facilitating communication “up and down the supply chain”
- Anticipating supply chain disruptions and providing alternatives
- Collaborating with customers on chemical substitution needs
- Supporting customer efforts toward eliminating the most toxic and dangerous chemicals from the supply chain

# Data Needed for REACH

Gathering data needed to support REACH compliance may require cross-functional support within a business:

## Categories of Data

- Chemical substance data
- Material composition data
- Sales channel data
- Supply chain data
- Product volumes sold
- Business process data

## Potential Data Sources

- Procurement personnel
- EHS personnel
- Supply chain managers
- Sales personnel
- R&D laboratory managers
- Manufacturing
- Operations
- Legal and contracts



# Getting Started



## Applicability assessment:

- High level determination of how REACH affects your business and your partners (chemical suppliers, importers, downstream users, components suppliers)
- Identify key criteria that will determine specific responsibilities for your company
- Define timeframes for compliance
- Determine high-level estimate of potential costs
- Define the business case for REACH and being proactive
  - REACH may result in disruptions of availability of chemicals
  - Could result in need to find and qualify substitute chemicals, which could take 1-2 years
  - Proactivity should contain costs and minimize disruptions
- Communicate results within your organization and build support



# Getting Started

## Assessing vulnerability of supply chain

- List your inventory of chemicals utilized in manufacturing
  - Determine supply chain partners and ultimate source of chemicals
  - Review for presence of SVHCs
  - Identify substances that are likely to be withdrawn due to REACH
  - Communicate with suppliers on their plans for supporting your chemicals through REACH
  - Initiate chemical substitution and qualification where risk of disruption is significant
- **Develop a REACH strategy**
    - Proportionate to applicability and potential business risk
    - Detailed action plan based on applicability assessment and supply chain vulnerability
    - Internal, external resources and expertise

# REACH Resources

European Commission REACH website:

- [http://ec.europa.eu/environment/chemicals/reach/reach\\_intro.htm](http://ec.europa.eu/environment/chemicals/reach/reach_intro.htm)

European Chemical Agency (ECHA) website:

- [http://ec.europa.eu/echa/home\\_en.html](http://ec.europa.eu/echa/home_en.html)

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[www.reach-answers.com](http://www.reach-answers.com)

**Questions?**