



## REACH and the Electronics Industry

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## Section 1

# REACH General Overview

## What is REACH?

- EU Regulation to establish integrated system for Registration, Evaluation and Authorization of Chemicals
- EU Chemicals Reform
  - consolidates the EU chemicals laws in one legislation
  - better protects human health and the environment
  - implements precautionary principle
- Shift of responsibility and costs to the private sector
- Establish European Chemicals Agency

*“REACH is one of the largest and most complex pieces of legislation ever attempted by the European Union”*



## REACH Allocation of Responsibilities

### Industry Responsibilities

- (Pre-)register substances
- Participate in substance registration process
- Provide information to users up the supply chain
- Exercise duty of care
- Notify use of certain substances
- Participate in substance authorization process
- Comply with authorizations and restrictions

### European Chemicals Agency Responsibilities

- Manage online repository of information submitted by industry
- Evaluate information
- Authorize or restrict use of certain substances



## REACH Basics

- 1,000 pages of legal text + technical annexes
- EU Regulation: directly binding throughout the 27 Member States
  - No Member States' implementation required
- 10 guidance documents for industry (in preparation); European Chemicals Bureau's REACH Implementation Projects ("RIPs")
- European Commission guidance documents: FAQs, Fact Sheet, "REACH in Brief," etc.

## Scope of REACH: Substances

- Applies to all substances whether manufactured, imported, used as intermediates or placed on the EU market either on their own, in preparations or in articles
- Extensive and complicated set of exemptions applies

***Substance: “chemical element and its compounds in the natural state or obtained by any manufacturing process ...”***



Slide 7

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Substance definition: obtained = produced

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## Substances in Preparations and Articles



***Preparation: “mixture or solution composed of two or more substances”***



***Article: “object which during production is given a special shape, surface or design which determines its function to a greater degree than does its chemical composition”***



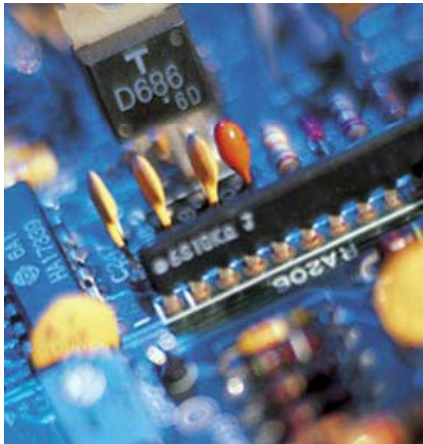
## Are Tech/Electronics Covered?

- REACH applies to:
  - EU importers of articles and substances
    - Importer = established within the EU and responsible for import
    - Article = includes finished goods or components
  - EU producers of articles
    - Producers = makes or assembles an article within the EU
  - EU “downstream users” of substances
    - Users of chemicals within the EU have several rights and duties
- Status of US company exporting to the EU
  - No direct legal liability but
  - May (most likely) need to assist its EU customers complying with REACH and may be required contractually to do so
    - *Similar to impacts of RoHS requirements on supply chain*
  - May decide “voluntarily” to appoint an EU Only Representative
    - *Remain competitive; compliance control*

## Two Electronics Industry Models

REACH responsibilities differ for:

- Companies who import “articles” into the EU
  - Articles that are intended to release substances
  - Articles that contain substances of very high concern
- Companies who have operations in the EU
  - Repair, servicing, assembly or manufacturing, in other words: companies that use chemical substances in the EU



## Section 2

# Implications for US High Tech Companies Importing Products in the EU

## Model 1: Importing Articles

- 2 “prongs” of requirements to worry about:
  - Substances “intended to be released under normal or reasonably foreseeable conditions of use”
    - Examples on next slide
  - Substances which are “of very high concern” are present
- If your customer is the EU importer, they will likely ask you for information about substances in your products or request that you verify REACH compliance

# Substances Intended to be Released from Articles(?)



## First Prong: Substances Intended to be Released: Registration

- Importer may need to submit a registration if
  - Any substance in your article is “intended to be released under normal or reasonably conditions of use” and
  - That substance is present in those articles in quantities totaling over 1 metric ton per year per producer/importer
- No registration required if the chemical manufacturer (or someone else) has already registered for your use
- You may decide to appoint an EU Only Representative to register yourself
  - Reminder: you are required to register yourself when your company is also based in the EU and deemed the importer!

## Registration Obligation

- Registration requirements include:
  - Technical Dossier:
    - Identity of manufacturer(s) or importer(s)
    - Identity of the substance
    - Information on manufacture and use(s) of the substance
    - Classification and labeling of the substance
    - Guidance on safe use of the substance
    - Data requirements (and costs) vary according to tonnage
  - Chemical Safety Report: For substances with annual volumes of more than 10 tons
- Registration tool: IUCLID 5 (International Uniform Chemicals Information Database) in combination with REACH-IT
  - Software not ready yet (probably June 2008)
- **Pre-registration online June 2008 – December 2008** (required to benefit from phased-in registration dates later)



## Second Prong: Substances of Very High Concern (“SVHCs”): Notification

- Importer may need to submit a notification to authorities if:
  - Any substance in your article is an SVHC identified on a “candidate list” to be published in June 2009,
  - That substance is present in your article in a concentration of 0.1% by weight, and
  - That substance is present in those articles in quantities totaling over 1 metric ton per year per producer/importer
- No notification required if the chemical manufacturer (or someone else) has already registered for your use
- Separate obligation to provide information on safe use (at minimum, name of the substance) to recipients of the article if 0.1% threshold is met
- Again: EU Only Representative / importer issue

## Notification Obligation

- **The information that must be notified includes**
  - The identity and contact details of the producer/importer;
  - The registration numbers for the substances, if available;
  - The identity of the substance;
  - The hazard classification of the substance;
  - A brief description of the use of the substance in the article and of the use of the article; and
  - The tonnage range of the substance, such as 1-10 tons, 10-100 tons, etc.
  
- **Notification requirement effective starting June 2011**  
(approx. 2 years after the "candidate list" is scheduled to be published for the first time)
  - 6 month window between the time a substance is newly listed in the candidate list and the effective compliance date for notification

## Example of SVHC

- Polybrominated Diphenyl Ethers (PBDEs) used as a flame retardant in
  - Housings for TVs, computers and other electronics, or
  - Polyurethane foams for mattresses, seat cushions, carpet padding, foam packaging, insulation materials
- May be substituted by Tetrabromobisphenol-A



## Example: Cell Phone Manufacturer



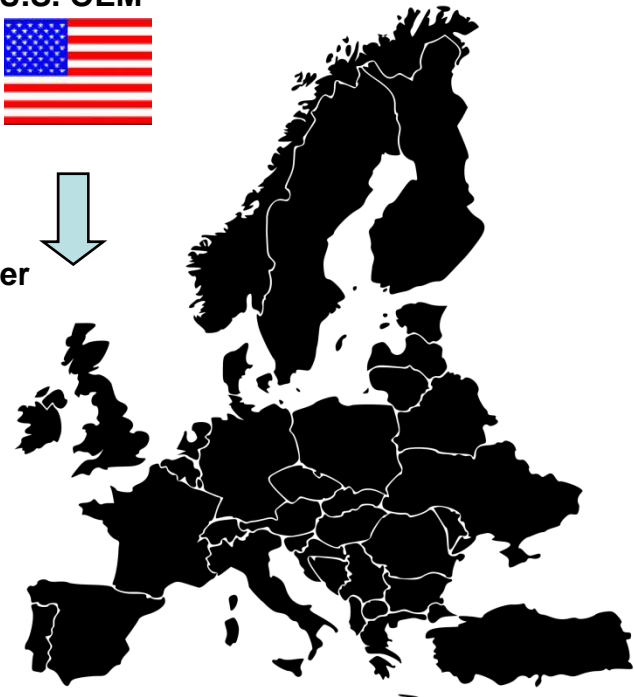
EU customer (Vodafone)  
wants to know: “Is this  
product compliant with  
REACH?”

- Substances intended to be released?
- SVHCs present?
  - 0.1%? 1 ton?

U.S. OEM

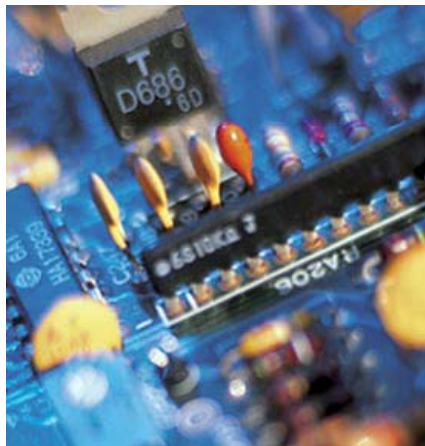


EU  
customer



## Open Issues Arising with Substances in Articles

- What will be on the SVHC “candidate list”?
- “Borderline cases” of intentional release
  - Pens, ink cartridges, firecrackers, car batteries
  - “Preparations” in containers instead? Any practical effect?
- “0.1% by weight” standard applicable to finished product, component or homogeneous materials?
- RIP 3.8 (Technical Guidance Document on Substances in Articles) will be updated (“when appropriate”) to clarify some of these issues
- Do you know what substances are in your products?
  - European Commission’s response: “REACH intends to fill in the current data gap about substances”



## Section 3

# Implications for US High Tech Companies that Repair, Service, Assemble or Manufacture Products in the EU

## Model 2: EU Operations

- You are a downstream user (“DU”) under REACH if you
  - Are established within the EU, and
  - Use any substances or preparations in the course of your industrial or professional activities
- Not regarded as DUs:
  - Distributors/retailers
  - Consumers
  - Parties outside the EU
- “Mere” DU vs. importer of substances or preparations
  - Process materials purchased within EU: You are a DU; EU chemical manufacturer must register (for your use)
  - Process materials imported from outside EU: You are an importer and must register (>1 tpy)

## DU Obligations

- Duty of care
  - Identify and apply proper measures to control risks (Safety Data Sheets)
  - Include this in information to customers
  - Communicate up the supply chain
  - Keep and update information
- RIP 3.5: Draft Technical Guidance Document for Downstream Users



## DU Right to Make Use Known to Supplier

- Make use known to supplier, in order to
  - Secure continued supply
  - Get your use included in Safety Data Sheets, exposure scenarios and chemical safety reports
- Dialogue in the supply chain in order to establish:
  - Standard descriptions of uses
  - Standard exposure scenarios
- Alternatively, the DU
  - Can choose to keep its use confidential
  - And prepare a chemical safety report for its own use
  - Conditions apply ( $\geq 1$  tpy and only in case SDS is required)

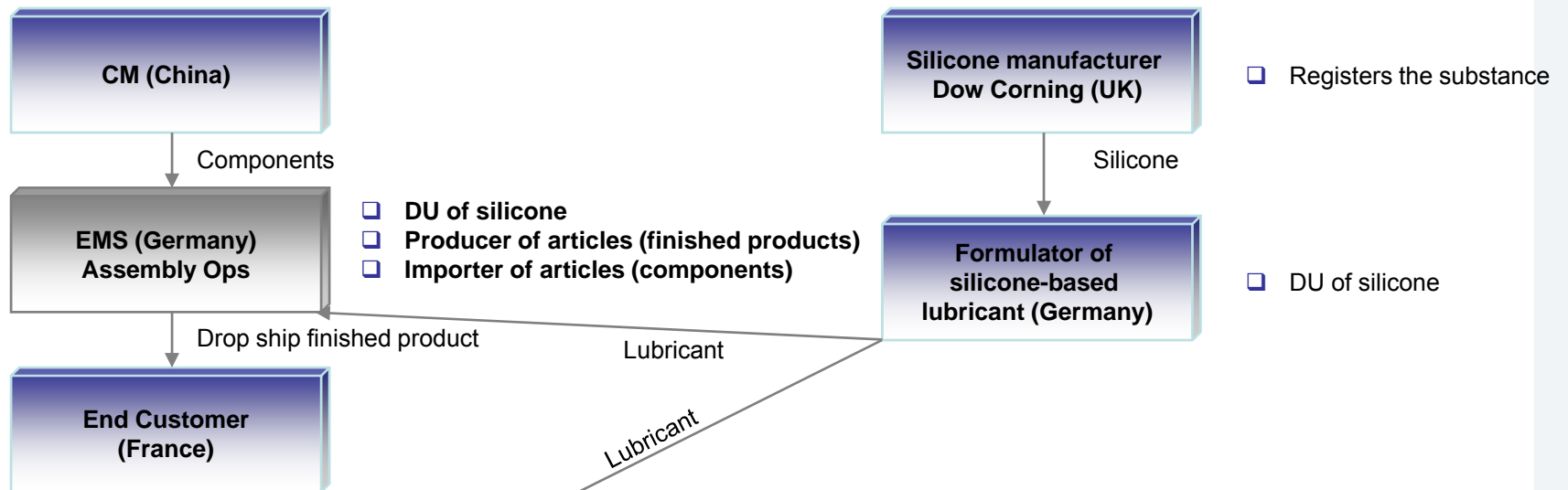


## Section 4

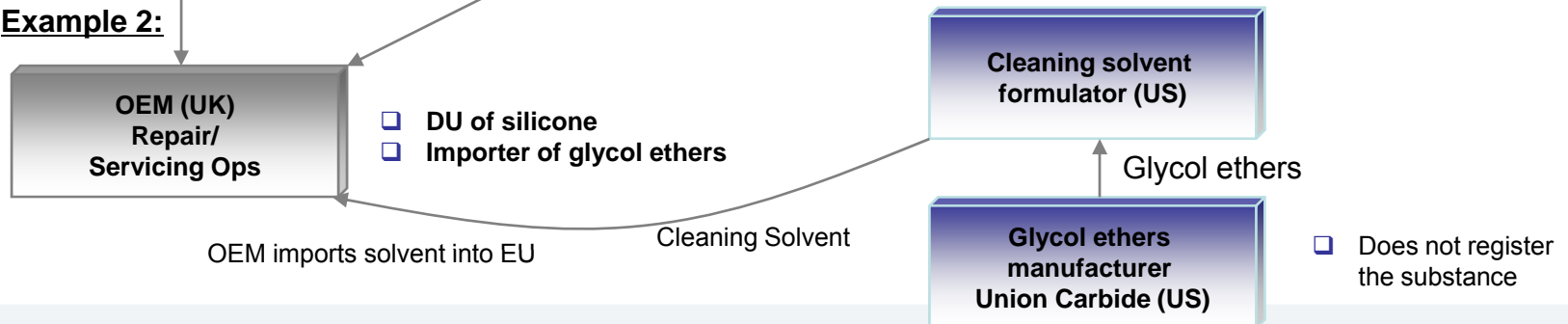
## Conclusions

# Illustrative REACH Impacts on High-Tech Supply Chain

## Example 1:



## Example 2:



## Compliance: Action Items

- Establish internal team and develop a compliance plan

### Importer of Articles

- Is there a release?
  - (Pre-)register with REACH agency starting June 2008
- SVHC
  - Track SVHC substances
  - Notify REACH agency by 2011

### Operations in the EU

- Track substances and preparations used or imported in EU
- Ensure that your chemical suppliers are including your use in their registrations

- Expand your supply chain communication and gather information on your suppliers' compliance programs
- Review and update your contracts to address REACH responsibilities
- Assess the financial impact of REACH compliance
- Prepare for changes in availability of substances

## Executive Focus



**EXECUTIVE DIRECTOR**  
**European Chemicals Agency, Helsinki**

The **REACH** Regulation, which enters into force on 1 June 2007, will establish a new regulatory framework for chemicals in the European Union. (see: <http://www.ec.europa.eu/enterprise/reach>). At the heart of REACH is the **European Chemicals Agency** (ECHA), located in Helsinki, Finland. ECHA will be responsible for managing technical, scientific and administrative aspects of REACH, and ensuring consistency in its application. It will provide the Member States and the EU institutions with high quality scientific and technical advice on chemicals issues.

As Executive Director, you will lead ECHA in its key early years and steer it through the scientific, technical and organisational challenges of establishing a complex regulatory process in a field that is politically sensitive and crucial to human health, the environment, economic competitiveness and innovation. You will be responsible for defining and implementing ECHA's work programme and managing its human, financial and technical resources. You will develop good relations with the EU institutions, the national competent authorities, industry and other stakeholders.

The full requirements for **qualifications and experience** are described in detail in the vacancy notice and include:

- national of an EU Member State
- university degree
- 15 years professional experience
- including 5 years management experience
- capacity to manage a major EU regulatory agency
- ability to lead and motivate a large multicultural and multilingual team
- knowledge of relevant regulatory policy and practice and experience of leadership in this field
- ability to cooperate and communicate with stakeholders

The term of office is 5 years, renewable once.

You will find the full vacancy notice and application form on the Commission's website at [http://www.ec.europa.eu/enterprise/reach/prop\\_jobs\\_en.htm](http://www.ec.europa.eu/enterprise/reach/prop_jobs_en.htm)  
Closing date for applications: 23 March 2007

<http://ec.europa.eu>

**Questions?**

**Thank  
You!**

## Useful Links

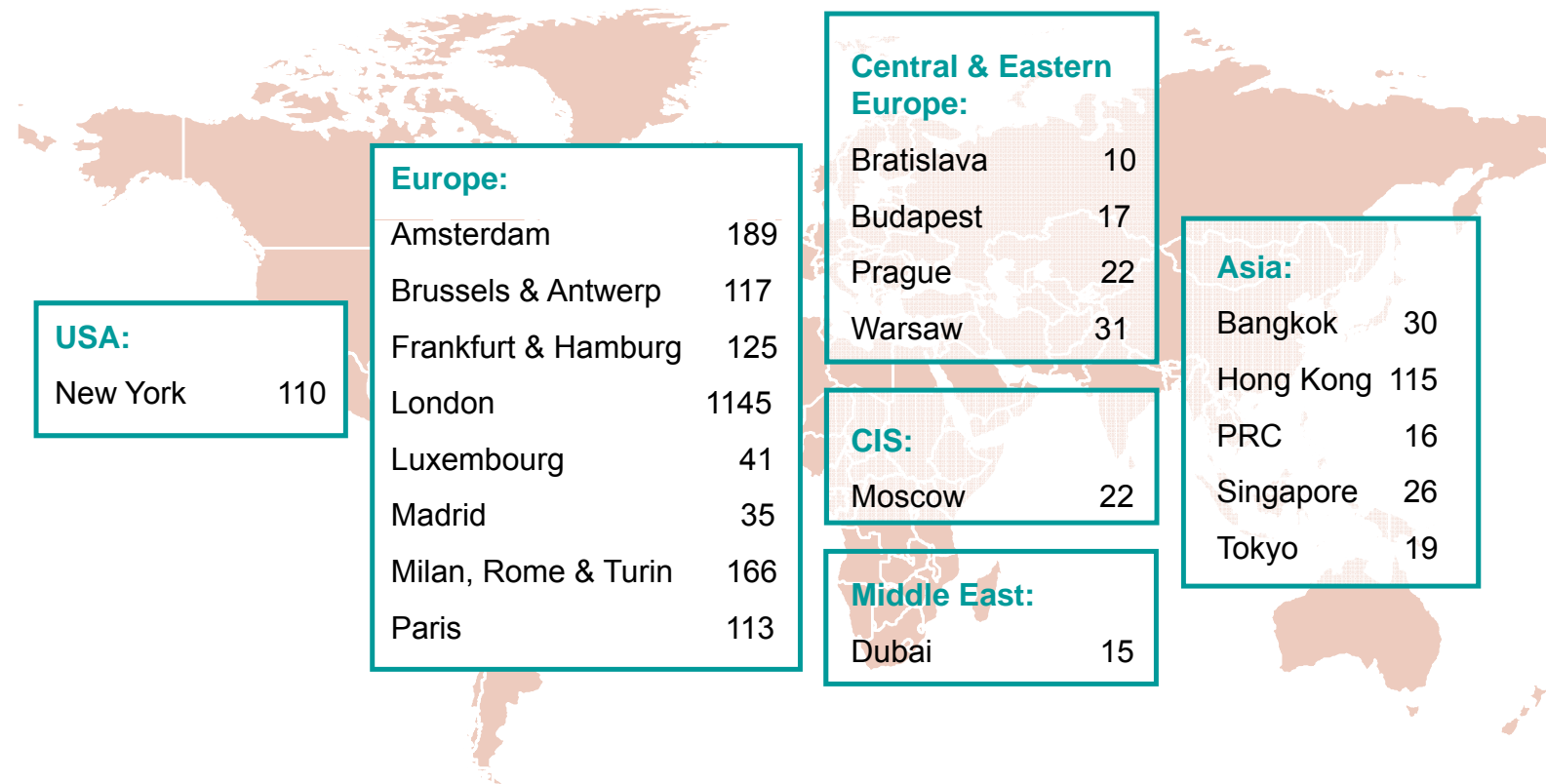
- Allen & Overy LLP
  - [www.allenoverly.com/reach](http://www.allenoverly.com/reach)
- European Chemicals Agency
  - <http://ec.europa.eu/echa/>
- IUCLID 5 Chemical Database
  - <http://ecbwbiu5.jrc.it/>
- European Chemicals Bureau
  - <http://ecb.jrc.it/reach>
- European Commission DG Environment
  - [http://ec.europa.eu/environment/chemicals/reach/reach\\_intro.htm](http://ec.europa.eu/environment/chemicals/reach/reach_intro.htm)

## Useful Links (cont'd)

- European Commission DG Enterprise
  - <http://ec.europa.eu/enterprise/reach>
- US Commerce
  - <http://www.buyusa.gov/europeanunion/reach.html>
- European Chemical Industry Council
  - <http://www.cefic.org/>
- ESIS: European Chemical Substances Information System
  - <http://ecb.jrc.it/esis/>
- CLEEN: Chemicals Legislation European Enforcement Network
  - <http://www.cleen-eu.net/>
- CAS Registry by the American Chemical Society
  - <http://info.cas.org/>



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by number of lawyers

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