

# REACH & WEEE

## Trends and A Brief Update



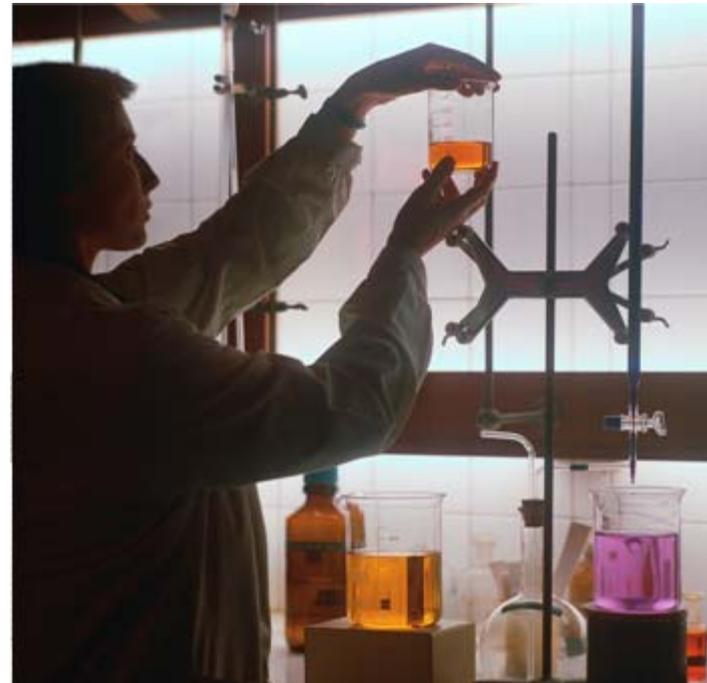
California Department of Toxic Substances Control & Intertek  
“The Greening of Electronics in a Global Economy”  
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# Outline

- Section 1 (Very Brief) Background on EU Law and Summary of Recent Trends
- Section 2 REACH: General Overview
- Section 3 REACH: Implications for US High Tech Companies
- Section 4 Reach: Issues and Challenges
- Section 5 WEEE: Brief Update

**Section 1**  
**(Very Brief) EU Law**  
**Background & Summary**  
**of Recent Trends**



## (Very Brief) EU Law Background

- EU Regulation: directly binding throughout 27 Member States
  - No Member States' implementation required
  - But inconsistent Member State legislation must be withdrawn/amended
- Enforcement (and some interpretation) by Member States
- Judicial powers on both Member State/EU level
  - National courts
  - European Court of Justice (incl. preliminary rulings/infringement procedures)

## Recent Trends

- Regulation of Products rather than/in addition to Processes
- Focus on market surveillance and industry responsibility
- Stepped up enforcement?
- EU Focus (at least rhetorical) on harmonizing and simplifying various EU environmental requirements: REACH, EUP, WEEE/RoHS, waste laws, “Marketing of Products Package”
- Precautionary Principle vs. Cost/Benefit Analysis

**Section 2**  
**REACH:**  
**General Overview**



# What is REACH?

- EU Regulation to establish integrated system for Registration, Evaluation and Authorization of Chemicals
- REACH was highly debated and reached by compromise:
  - Typical for EU decision making?
  - Consolidates/replaces over 40 pieces of EU legislation
  - Significant shift in EU chemicals regime
  - Establishes European Chemicals Agency (ECHA)
- Underlying Principles:
  - Precautionary Principle
  - Producer Responsibility – shifts responsibility/costs to private sector
  - No Data, No Market
  - One Substance, One Registration
  - Principal focus on environmental protection... or enhancing competitiveness of EU chemicals industry?

## Scope: 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
- It is not just “traditional chemicals” that are caught

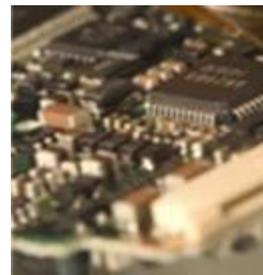
***Substance: “chemical element and its compounds in the natural state or obtained by any manufacturing process ...”***



## Scope: 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”**



## Scope: REACH's Limits

- REACH does not apply to:
  - Radioactive substances
  - Non-isolated intermediates
  - Waste
  - Defense-related substances (on their own, in preparations or in articles) specifically exempted by Member States
  - Transport of dangerous substances
  - Substances subject to customs supervision (*i.e.*, not put on the market) in view of re-exportation

## Scope: Exemptions

- Very complex set of specific “partial” exemptions
- Exempted from REACH registration (but subject to other REACH provisions):
  - Substances that are considered to cause minimum risk (Annex IV; includes water (pure), carbon, sunflower oil, cellulose pulp, etc.)
  - Substances for which registration is deemed inappropriate or unnecessary (Annex V; includes minerals, ores, cement clinker, natural gas, oxygen, nitrogen, etc.)
  - Polymers
  - Substances already registered (“notified”) (pre-registration doesn’t count!) in accordance with REACH’s predecessor (Dir. 67/548/EEC) and biocides/pesticides: regarded as being registered

## Scope: More on Exemptions

- Note! Other specific “partial” exemptions may apply, including:
  - Use of substances regulated by other legislation, including food and animal nutrition and substances in medicinal (human or veterinary) products
  - Isolated intermediates (less stringent registration regime)
  - Cosmetics/PPORD

# Principal Requirements

- **Registration/pre-registration** of substances
  - Pre-registration period 1 June -1 December 2008 designed to give industry the opportunity to take advantage of extended registration deadlines
  - Notification of Substances of Very High Concern (SVHCs) in articles
- **Evaluation** of registrations/substances
- **Authorization** for use of SVHCs
- **Restrictions** to prohibit or control risks of use of certain dangerous substances

# Who has obligations?

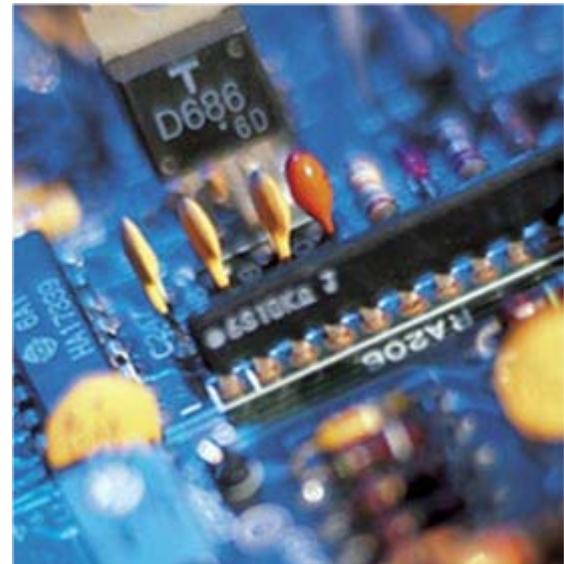
- REACH imposes obligations on manufacturers, importers, distributors and downstream users of substances and articles containing substances
  - Importers (often includes distributors) - established within the EU and responsible for physical introduction of substances into the Customs Territory of the Community
    - Article = includes finished goods or components
  - Producers of articles
    - Article producers make or assemble articles within the EU

# Are US Companies Caught?

- Status of US company exporting to the EU
  - No direct legal liability
  - Non-EU companies cannot pre-register/register substances under REACH but
  - May (most likely) need to assist EU customers complying with REACH – contract requirements?
    - *Similar to impacts of RoHS requirements on supply chain*
  - May decide “voluntarily” to appoint an EU Only Representative to carry out pre-registration/registration on behalf of its EU customers
    - *Remain competitive; compliance control; ensure products can be sold in the EU*

## Section 3

### REACH: Implications for US High Tech Companies



# How are US Electronics Companies Caught?

- REACH responsibilities differ for:
  - Companies that import “articles” into the EU
    - Intentional release?
    - No intentional release but SVHCs?
  - Companies that have operations in the EU
    - Use chemicals during repair, service, assembly, or manufacturing

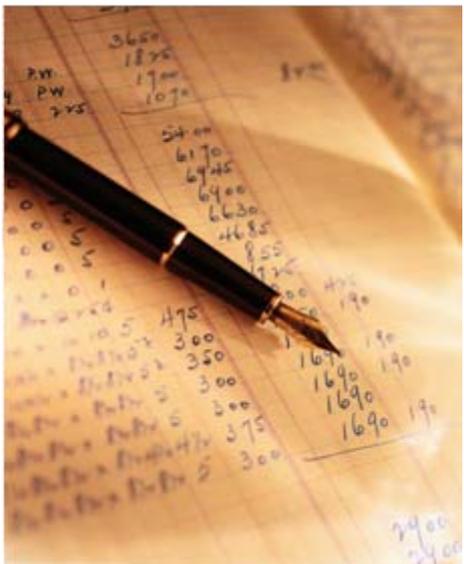
## Implications for High-Tech Companies that Import “Articles” into the EU

- 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 present which are “of very high concern”
- 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

# 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 on behalf of your importers
  - Reminder: you are only required to register yourself if your company is also based/established in the EU and is either deemed to be an importer or is carrying out manufacture within the EU!

# Substances Intended to be Released from Articles(?)



## Pre-registration

- EU manufacturers or importers were permitted to take advantage of extended deadlines for registration if they pre-registered all relevant phase-in (existing) substances with ECHA between the **1 June 2008 – 1 December 2008**
- Pre-registration did not involve any fee and required only basic information about the substance and the registrant to be submitted online using REACH-IT
- Phase-in substances which were not pre-registered by 1 December 2008 will not be able to be placed on the market without a full registration having been completed

## Second Prong: 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” the first version of which was released in October 2008 and will be updated approximately twice a year thereafter.
  - 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

## Second Prong: SVHCs - Notification

- No notification required if the chemical manufacturer (or somebody else) has already registered that substance 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 (**Article 33**)
- Again: EU Only Representative / importer issue
- **Notification requirement effective starting June 2011**
  - 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



## Open Issues Arising with Substances in Articles (1)

- SVHC “candidate list” published in October 2008
- “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?
- 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”

## Open Issues Arising with Substances in Articles (2)

- Communication obligations for articles containing SVHC (Article 33)
  - General obligation towards “recipients
  - Upon request by “consumers” – who are they?
- “if available”: presence of SVHC, information on safe use
  - What if the info is not available?
  - Diligence requirements (may include chemical testing, “as a last resort”
  - Obligation/need to update
- Lots of NGO activity in this area – communication is important (legal and reputational issues)

# Implications for High-Tech Companies That Have EU Operations

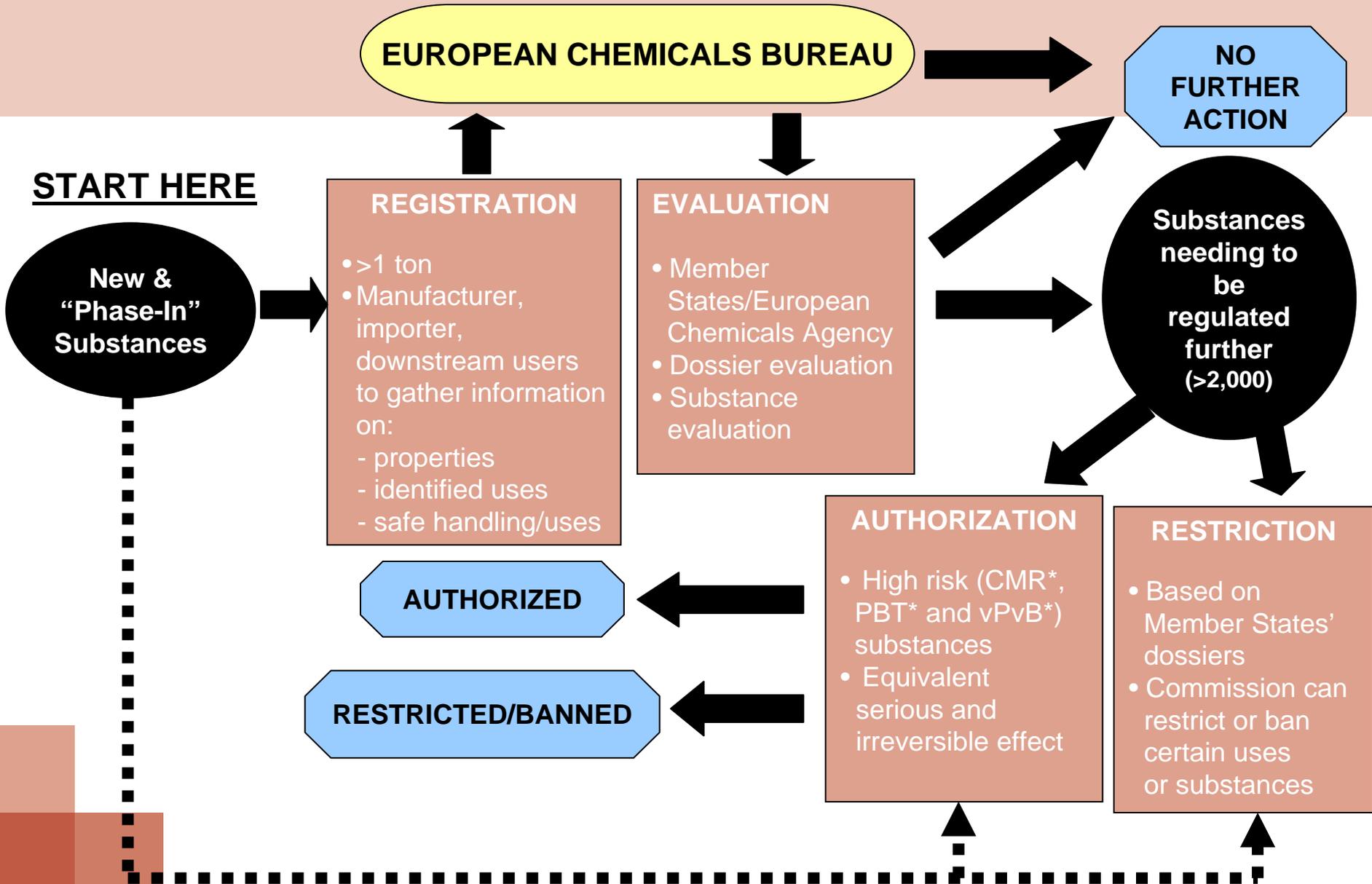
- You are a downstream user (“DU”) under REACH if you
  - Are established within the EU, and
  - Use any substances or preparations in the course of your industrial or professional activities
- Not regarded as DUs:
  - Distributors/retailers
  - Consumers
  - Parties outside the EU
- “Mere” DU vs. importer 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)



**EUROPEAN CHEMICALS BUREAU**

**NO FURTHER ACTION**

**START HERE**

**New & "Phase-In" Substances**

**REGISTRATION**

- >1 ton
- Manufacturer, importer, downstream users to gather information on:
  - properties
  - identified uses
  - safe handling/uses

**EVALUATION**

- Member States/European Chemicals Agency
- Dossier evaluation
- Substance evaluation

**Substances needing to be regulated further (>2,000)**

**AUTHORIZATION**

- High risk (CMR\*, PBT\* and vPvB\*) substances
- Equivalent serious and irreversible effect

**RESTRICTION**

- Based on Member States' dossiers
- Commission can restrict or ban certain uses or substances

**AUTHORIZED**

**RESTRICTED/BANNED**

\*Carcinogenic, Mutagenic or Reprotoxic; Persistent Bio-accumulative and Toxic; very Persistent and very Bio-accumulative.

**Section 4**  
**REACH: Issues &  
Challenges**



# Data Sharing & Competition

- Data sharing in consortia
  - Confidentiality/trade secrets
  - Lead registrant
  - New members and “free riders”
  - Fees
  - Disputes
- Competition (*i.e.*, anti-trust)

## More Issues and Challenges

- Supply chain management
- Information – obtaining, managing, sharing, protecting, validating
- Strategic planning
- M&A
- Securities disclosure
- Compliance management
- REACH copycats.....right here in California...

**Section 5**  
**WEEE: Brief Update**



## WEEE – Brief Update on New Proposal (1)

- New proposal for WEEE (in conjunction with RoHS)
- Harmonize producer registries
  - Producer can register/report in one Member State for all activities across the EU
  - Common format & deadlines for registration and reporting
- Beef up Enforcement
  - Specific rules on MS inspections & monitoring activities
  - Focus on exports to non-EU jurisdictions
  - Paperwork for “used EEE” vs. “WEEE”

## WEEE – Brief Update on New Proposal (2)

- Increased Targets
  - Recycling and re-use targets +5%
  - Minimum collection rate of 65% for all WEEE (starting 2016)
- Useful Clarifications
  - How to classify household vs. non-household WEEE (future comitology decision)
  - POTM = Community market
  - Quantity calculations = by weight
    - Common calculation methodology is forthcoming
    - Separate WEEE costs can be shown to **all** purchasers (B2C **and** B2B)

**Questions?**

**Thank  
You!**

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## Executive Focus



EUROPEAN COMMISSION

# 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/prep-jobs\\_en.htm](http://www.ec.europa.eu/enterprise/reach/prep-jobs_en.htm)

Closing date for applications: 23 March 2007

<http://ec.europa.eu>