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The new EU Legislation on Chemicals Management

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Delegation of the European Commission to the US

Why do we need REACH in the EU?

Current chemicals management system is inefficient

- Difficult to identify risks + difficult to address risks:
  - Lack of information about most chemicals on the market
  - Burden of proof on public authorities
  - No efficient instrument in place to deal with problematic substances
- Lack of incentives for innovation
- Lack of confidence in chemicals and the chemicals industry.

The Current EU Chemicals Policy

Issues

- New substances for marketing/import ≥ 10 kg to be notified with testing data according to volume bracket to Competent Authority in a Member State, reaction within 60 days
- Legislation works OK, but new substances are too heavily regulated, 0.01 % of marketed volume
- Existing substances ‘grandfathered in’ and virtually not regulated, 99.9 % of marketed volume

Burden of the Past

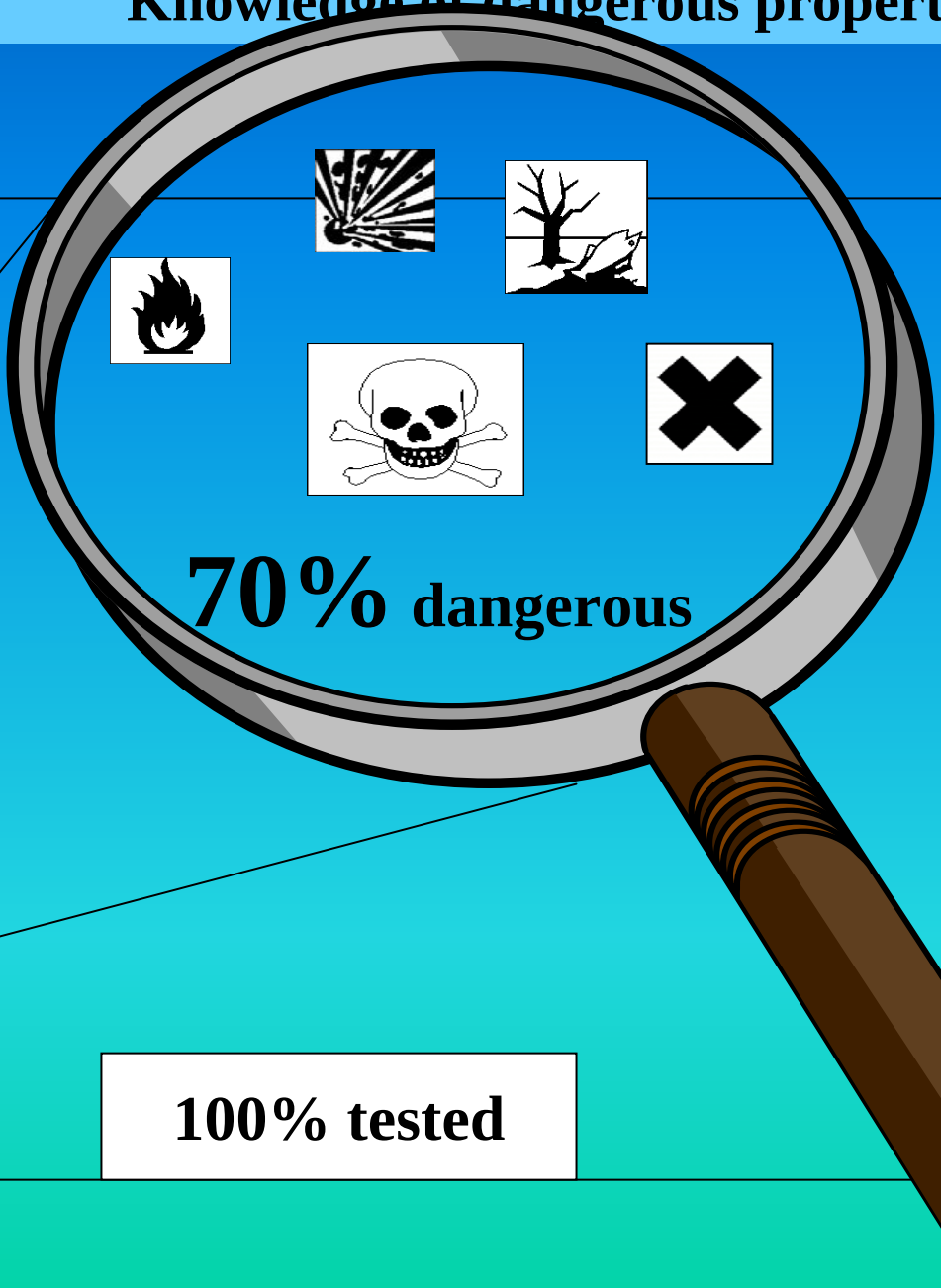
The Current EU Chemicals Policy

Existing substances

- Existing substances can be used without testing (100,106 existing substances registered in EINECS = closed list of 1981)
- Estimate: approximately 70,000 on the market
- Burden of proof on public authorities
- No efficient instrument to ensure safe use of the most problematic substances
- Risk assessments too slow: assessment of few substances completed
- Insufficient resources on the part of Member States: heavy delays (4 to 6 years for some substances)
- Disincentive for innovation and substitution

Lack of Confidence in Chemicals

New substances –
Knowledge of dangerous properties



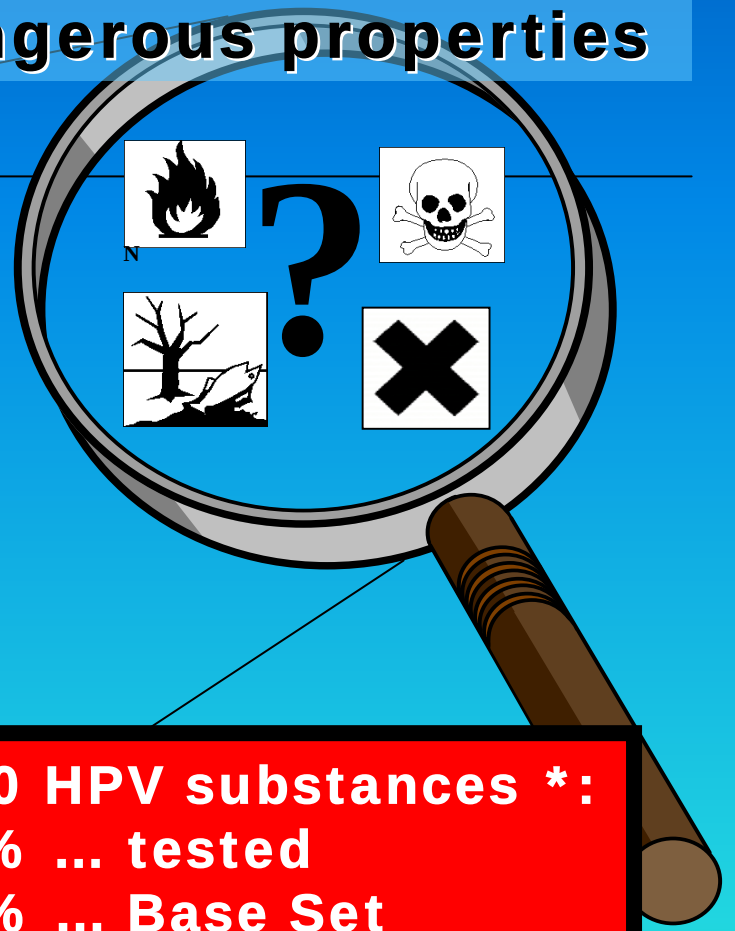
70% dangerous

3.800
new substances

100% tested

Existing substances

Knowledge of dangerous properties



30,000
'existing' substances > 1 metric tonne/m/y

2600 HPV substances *:
3 % ... tested
11 % ... Base Set
15 % ... almost Base Set
15 % ... no data
56 % ... often data for acute toxicity

*... Evaluation by the ECB.
~~HPV = high production volume(>= 1000 tonnes/year/~~ manufacturer). These substances cover over 95% of the chemicals on the market.

Example: Phthalates in baby toys

- Risk assessment was on its way but not ready: alarming interim results
- Preliminary evaluation by Scientific Committee
- In view of potential irreversible effects, Precautionary Principle was applied: Temporary restriction, to be reviewed every 6 months on basis of state of the art on science
- Finally: Commission proposal for permanent ban

THE PRECAUTIONARY PRINCIPLE

BONE OF CONTENTION

- Politics versus science?
  - NO, in the EU application of precaution is based on the science available!
- Decision on PP is a TEMPORARY measure to be looked at/ renewed in the light of new information

Precaution in EU Treaty

US Toxic Substances Control Act of 1976

- Distinguishes new from existing substances, but in a different way than in the EU:
  - A new chemical substance is any chemical substance which is not (yet) included in the chemical substance list (CSI)
  - CSI is a list of **all** chemical substances in commerce prior to 1979 and those that have come on the market (about 81,000 chemicals with 27,000 polymers)
  - New chemicals amount to about 1% by volume of chemicals on market.

Testing and Modeling

- TSCA compels EPA administrator to testing of a chemical substance or mixture, new or existing if:
- The subject chemical or mixture "may present an unreasonable risk (hazard/risk finding) **or**
- The chemical will be produced in substantial quantities and either may enter the environment in substantial quantities or lead to significant human exposure (exposure finding) **and**
- Inadequate data exist for use in risk assessment **and**
- Testing is necessary to develop the needed data

RESULT: EPA has developed several modeling techniques to replace the need for testing, including Structural Activity Relationships (SARs)

Risk Assessment and Risk Management of Existing Substances

- EPA must demonstrate that one ore more activities involving a substance or mixture presents or will present an unreasonable risk
- EPA must evaluate health and environmental effects, exposure, benefits of the substance, availability of substitutes and economic effects (must chose least burdensome form of regulation and balance costs and benefits)
- Actions from prohibitions to risk communications and use of consent orders and preliminary notices

Risk Assessment and Risk Management of Existing Substances

- EPA's experience with asbestos demonstrates the high hurdle of the 'unreasonable risk' requirement of TSCA. Circuit Court of Appeals ruled that EPA:
  - Had not proposed the least burdensome legislation
  - Had not demonstrated a reasonable basis for regulatory action
  - Had not adequately balanced benefits and costs of the restriction
- To date only 5 chemicals/uses restricted (CFCs, PCBs, Dioxin in production waste, hexavalent chromium and some new uses of asbestos)

Addressing the data gap: High Production Volume Challenge

- In response to EPA Data Availability report EPA and industry agreed the HPV challenge for industry to provide basic testing data and robust summaries
- 3000 HPV chemicals
  - 1900 sponsored
  - 500 orphans (some are no longer HPV)
  - Represents about 99% of total tonnage
- Results available on all sponsored chemicals
  - What to do with results in terms of risk management
  - Extension to lower volume chemicals
  - Orphans

Common features concerning existing substances

- "Existing" chemicals were 'grandfathered in'
- Are seen as safe until government demonstrates that they present an unreasonable risk: a huge task because of enormous gap in information
- Limited and very slow results on risk assessments, high costs on the regulator. This will shift under REACH in the EU
- Few bans and restrictions and a disincentive to introduce safer chemicals as substitutes for 'old' chemicals

Common features of current EU and US systems

- Industry not very proactively providing information/testing on chemicals on the market before 1979 respectively 1981
- Overuse claim of Confidential Business Information
- “New” chemicals legislation as such a success story but covers only a very small fraction of the chemical universe

A New EU Chemicals Policy

Objectives of REACH

- Sustainable Development
  - Protection of human health and the environment
  - Maintain/enhance innovation/competitiveness
  - Maintain the Internal Market
  - Increased transparency and consumer awareness
  - Integration with international efforts
  - Promotion of non-animal testing
  - Conformity with WTO obligations

Substitution and precaution underpin system

REACH – Key elements

- **Scope: all** substances ≥ 1 tonne/yr per manufacturer/importer
- **Exemptions:** for some substances for parts of REACH (polymers, regulated substances) or reduced requirements (isolated intermediates on site or limited transport). ELINCS substances are automatically registered unless production volume changed
- **Registration** by producer, importer *or Only Representative*
- **Evaluation** of some substances
- **Authorization** only for substances of very high concern. *NO tonnage threshold!!*
- **Restrictions -** the safety net (Community wide action)
- **Agency** to efficiently manage the system

Focus on priorities:

Substances with high volumes and those of greatest concern!

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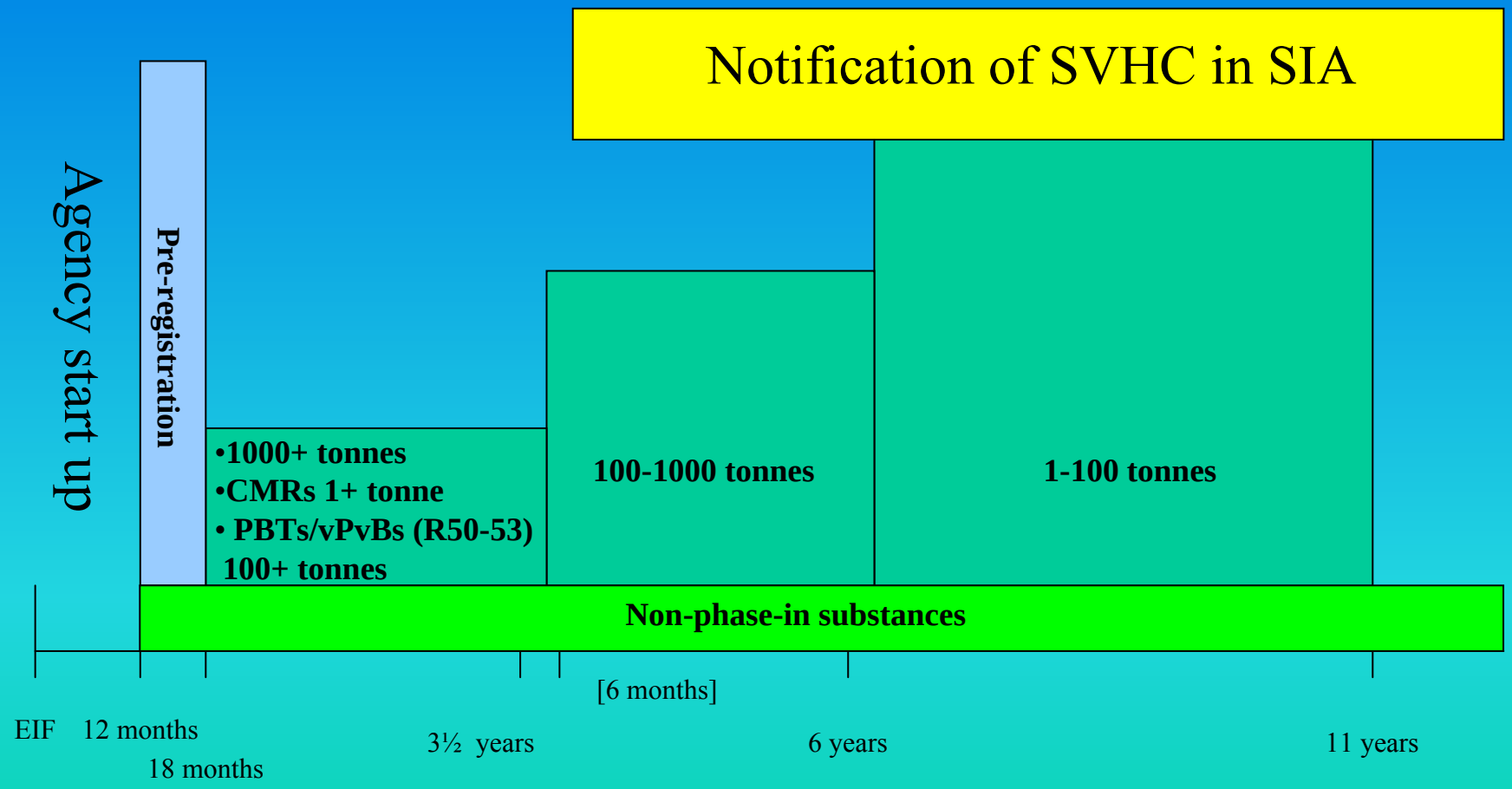
Registration Timeline



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Generation of Information

F L E X I B I L I T Y

- (Q)SARs
- Use of category approaches
- Analogs, read across
- Available data (non-EU, GLP, non-GLP)
- Exposure based waiving (Annexes VII and VIII)
- Historical human data
- Data sharing (existing and new)

Testing (*in vitro*, *in vivo*) as a last resort

Registration – Substances in Articles

- Registration of substances intentionally released
  - Substance present above 1 tonne
  - Agency may require registration for substances which are not intentionally released from an article but present a risk.
- Notification of substances of very high concern if
  - SVHC present above 1 tonne
  - SVHC present above a concentration limit of 0,1%
  - Exposure of the public or the environment during the full life cycle cannot be excluded
  - Applies 6 months after substance is listed on authorisation candidate list.

Authorization

Ensure risks from substances of very high concern are properly controlled and eventually substituted.

- Substances of very high concern:
  - Carcinogenic, mutagenic, reprotoxic (CMR)
  - Persistent, bioaccumulative and toxic (PBT)
  - Very persistent and very bioaccumulative (vPvB)
  - Substances of "equivalent concern for which there is scientific evidence of probable serious effects"

Information through the supply chain

Improve risk management

- What:
  - Expanded Material Safety Data Sheets with information from Chemical Safety Reports (exposure scenarios)
  - Information on risk management, authorizations, restrictions, registration number etc.
  - Information up the supply chain on new hazards
- Result?
  - more information on risks
  - downstream users benefit
  - dialogue up/down the supply chain-encouraged/stimulated

Downstream Users

- Manufacturer/importer has to cover all uses identified by downstream users.
- Downstream user benefits from choice of:
  - supplier carrying out assessment, or
  - for confidentiality reasons doing own assessment.
- Downstream user will just have to:
  - implement supplier's Risk Reduction Measures for identified uses
- Downstream user will have to:
  - perform assessments only for 'unidentified uses' (using supplier hazard information)
  - inform Agency of 'unidentified uses' ≥ 1 tonne

REACH Implementation

- End 2006 – Publication in the OJ
- June 2007 – Entry into force of REACH
  – Setting up the Agency in Helsinki
- June 2008 – Agency operational
- June 2010 – First substances prioritised for **authorisation**
- June 2010 – 'New' **restrictions**
- End 2010 – First **registration** deadline for >1000t &CMR
- End 2018 – Last registration deadline for >1t

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The Interim Strategy

4 basic work elements:

- Re-focus Current Activities → Aligning Dir. 67/548 and Reg. 793/93 with REACH
- Preparing for REACH → Developing Guidance Documents and Software Tools for efficient, transparent and consistent implementation
- Strategic Partnerships → "Working together, preparing for REACH"
- Setting up the Agency → Finland: Practical aspects; COM: Organisation

The Interim Strategy prepares ALL stakeholders for a Sustainable REACH Implementation

The RIPs

- REACH Implementation Projects (RIPs):
  - RIP 1: Process descriptions (available on ENV website)
  - RIP 2: Development of IT systems (REACH-IT)
  - RIP 3/4: Guidance Documents (industry/authorities)
  - RIP 5/6: Preparation for start-up of Agency
  - RIP 7: Commission preparations

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RIP-3

3.1: Preparing the registration dossier

3.2: Preparing the CSR

3.3: Information requirements

3.4: Guidance on data-sharing

3.5: Guidance for downstream users

3.6: Guidance on C&L under GHS

3.7: Guidance on applications for authorization

3.8: Requirements for articles

3.9: Guidance on SEA

3.10: Guidance on checking substance ID

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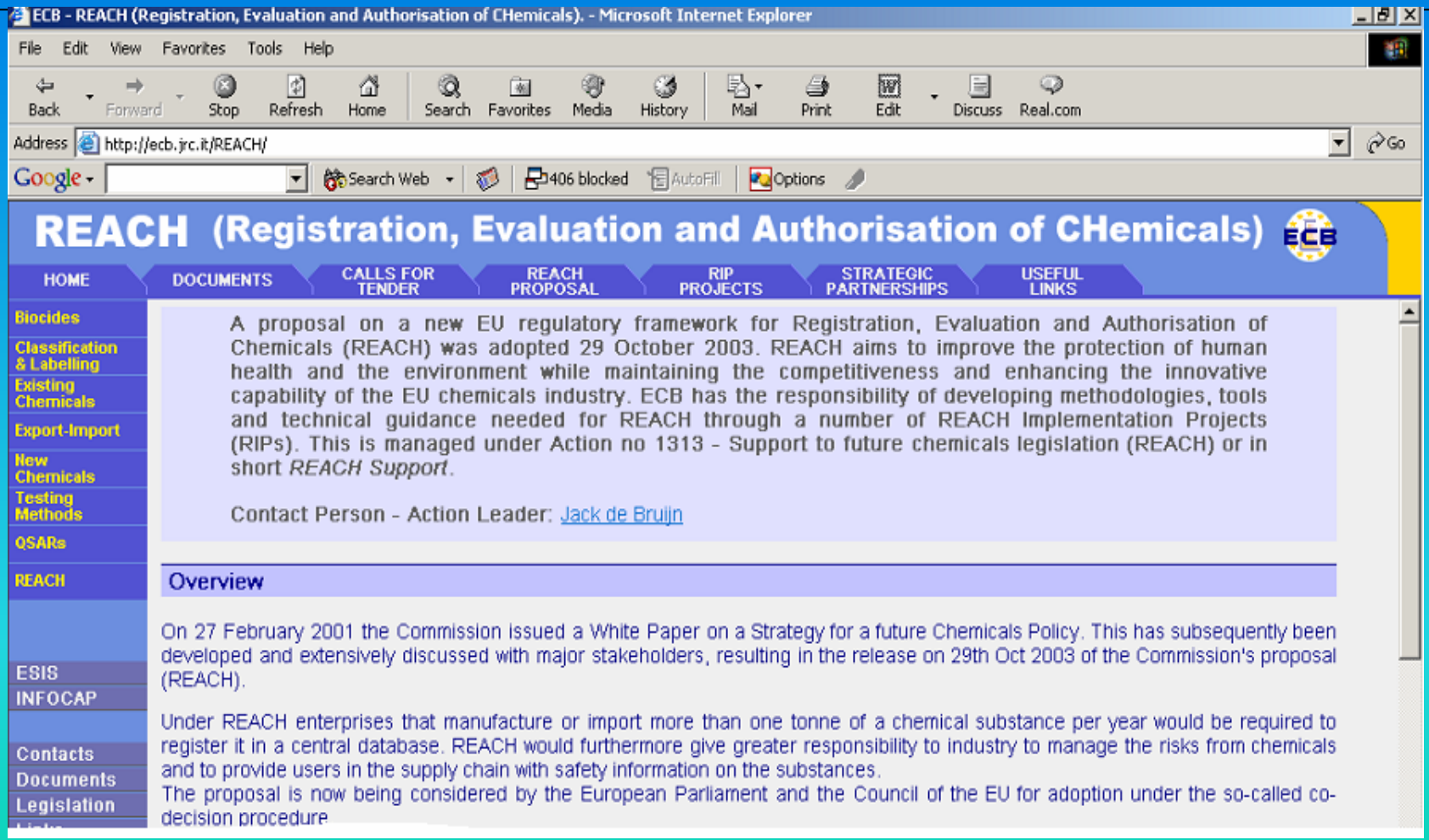
Further information on RIPs

http://ecb.jrc.it/REACH/



Impact – Costs and Benefits

- REACH will cost between € 2,8 billion and € 6 billion over 11 years depending on how many substances will be withdrawn, how much info industry has and how quickly in vitro tests and (Q) SARS will be developed
- Costs reductions for potentially vulnerable lower volume substances
- Foster Innovation
  - Lower requirement for new substances;
  - More Flexible R&D provisions
- Health benefits at €50 billion over 30 years
- Prevention of occupational skin and respiratory diseases (€90 billion over 30 years)
- Benefits to the Environment (at least €9 billion saved cost)

Liability and Costs

1. EPA Fines Teflon Maker DuPont for Chemical Cover-Up:

EPA fines Teflon maker DuPont $16.5 million for covering up studies showing it was polluting drinking water and newborn babies with an indestructible chemical that causes cancer, birth defects and other serious health problems in animals.

2. Asbestos 'settlement' with insurance companies costed Halliburton $ 5 billion

Interplay U.S. and EU legislation (1)

- The EU and the US face similar issues:

1. Limited action and low information on properties of existing chemicals;
2. poor knowledge about uses, hence risks;
3. high regulatory focus on new chemicals (very small fraction of chemicals in commerce).

- Positive aspects of U.S. system:

1. use of modeling ((Q) SARs) and grouping of chemicals;
2. experience with and rules for R&D, polymers, Low volume, Low Release and Exposure

Interplay US and EU legislation (2)

- REACH will provide an important driver to overhaul TSCA (Senators Clinton and Lautenberg) and action at state level (California, Massachusetts): consequences for domestic producers and also for importers to the U.S, for instance from Asia
- REACH will provide lots of data

1. on properties of HPVs and lower tonnage chemicals;
2. chemical use information;
3. exposure scenarios;
4. validated computer models and in vitro testing on certain end points

- RESULT: Better risk assessment and management in the EU, the U.S. and elsewhere.

State initiatives: right-to-know, process or product oriented policies

- Labeling, precaution, imminent overhaul of legislation in California
- High Hazard Chemicals program on basis of Toxic Used Reduction Act (TURA) in Massachusetts
- PBTs, in particular brominated flame retardants – Washington State, Maine and Oregon
- Local procurement programs (e.g. Seattle)
- Mercury bans at local, state, regional level (e.g. Washington State, Maine)

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Summary of REACH

- REACH is a single coherent system for new (non phase-in) and existing (phase–in) chemicals for substances produced/imported over 1 metric tonne per year/per m/i.
- Chemical industry responsible for registration, information, draft risk management measures to ensure that chemicals can be handled safely on site and by downstream users
- Downstream users to communicate use information to producers/importers, hence better understanding of risk profile for all involved
- Producers/importers to provide more tailor made information to downstream users in MSDS than today
- Result: More and better information and communication up and down the supply chain and hence better risk management by industry
- Authorities in monitoring and control mode, except for restrictions and communication to the general public

Information

EUROPA

Thank you!

http://europa.eu.int/comm/environment/chemicals/index.htm

http://europa.eu.int/comm/enterprise/chemicals/index.htm