



REACH

The New EU Chemicals Legislation

REACH *In Practice*, Steptoe & Johnson LLP,
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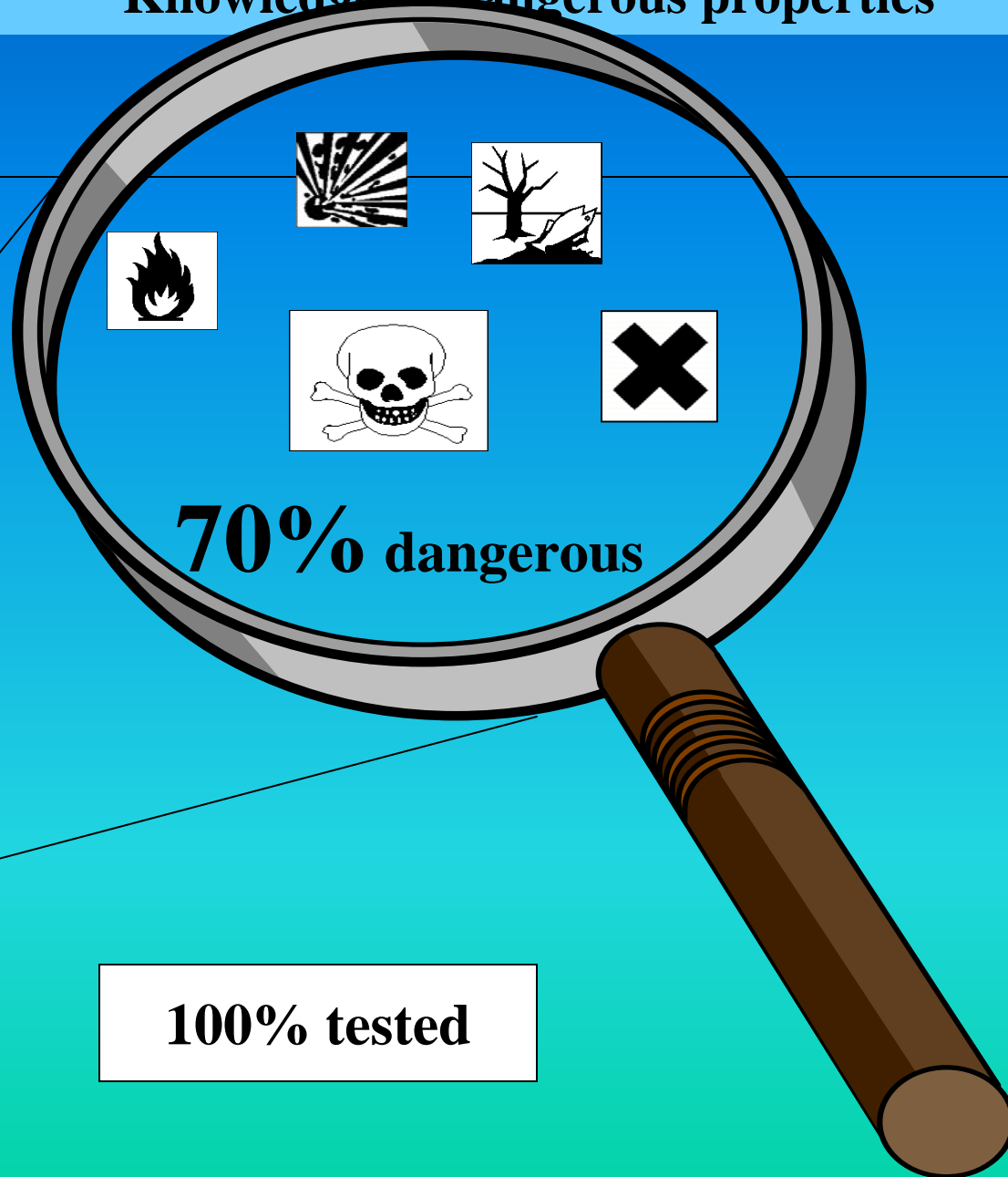
Why do we need REACH?

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 lies on public authorities
 - No efficient instrument is in place to deal with problematic substances
- Lack of incentives for innovation
- Lack of confidence in chemicals and the chemicals industry.



New substances – Knowledge of dangerous properties



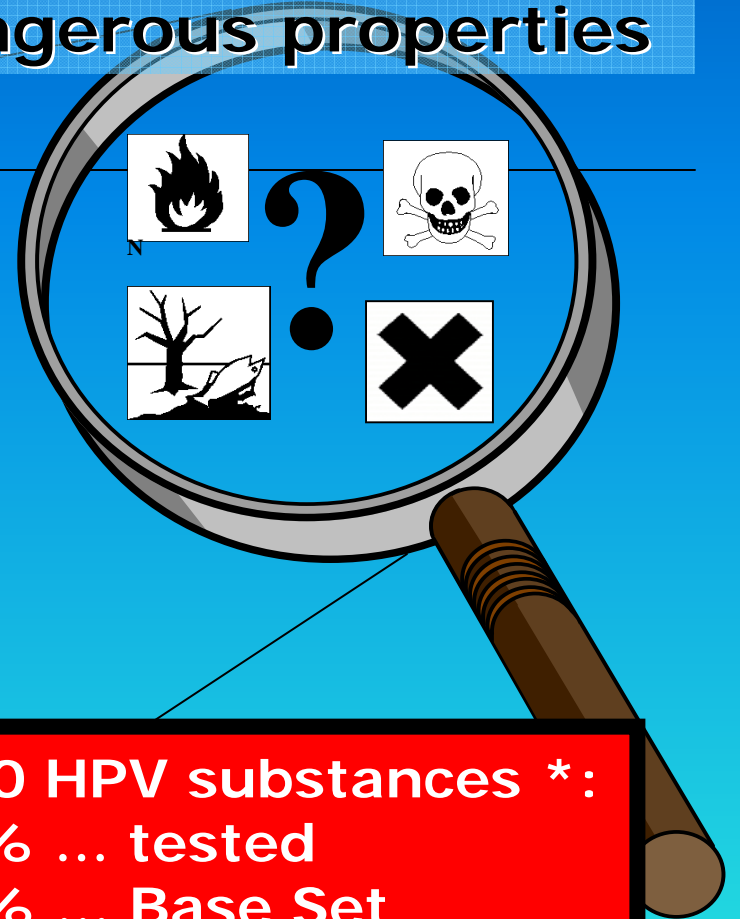
3.500
new substances

100% tested



Existing substances

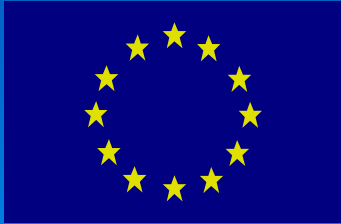
Knowledge of dangerous properties



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.

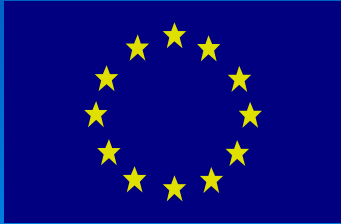


REACH – Key elements

- Registration of substances ≥ 1 tonne/yr
- Increased information and communication throughout the supply chain
- Evaluation of some substances
- Authorization only for substances of very high concern
- Restrictions - the safety net (Community wide action)
- Agency to efficiently manage system

Focus on priorities:

Substances with high volumes and those of greatest concern!



Registration

Objective: Ensure industry adequately manages risks from substances

□ What?

- Tonnage based
- Registration deadlines: 3½-6-11 years
- Limited information for intermediates and exemption for polymers
- Limited information for research and development (PPORD)
- Substances in Articles.

□ How?

- Manufacturer/importer obtains or generates adequate information
- Electronic dossier submitted to Agency
- Certain non-confidential information to central (largely public) database.



Registration Requirements (1)

Elements of a registration dossier:

- 1 tonne and above: Intrinsic properties
- 10 tonnes and above: Chemical Safety Report (CSR)

Tiered testing:

- 1-10 tonnes: Available information + Phys-chem properties in Annex VII (full Annex VII for prioritised substances)
- 10-100 tonnes: Annexes VII and VIII.
- 100-1000 tonnes: Annexes VII and VIII; testing proposals for information in Annex IX
- > 1000 tonnes: Annexes VII and VIII; testing proposals for information in Annex IX and X



Registration Requirements (2)

	Health	Environment
1-10t prioritised	<ul style="list-style-type: none"> <input type="checkbox"/> <i>In vitro</i> skin and eye irritation <input type="checkbox"/> Skin sensitiation <input type="checkbox"/> <i>In vitro</i> mutagenicity <input type="checkbox"/> Acute toxicity (one route) 	<ul style="list-style-type: none"> <input type="checkbox"/> Acute aquatic toxicity – Daphnia <input type="checkbox"/> Biodegradation – biodegradability and hydrolysis <input type="checkbox"/> Acute aquatic toxicity – Algae
10- 100t	<ul style="list-style-type: none"> <input type="checkbox"/> <i>In vivo</i> skin and eye irritation <input type="checkbox"/> Further <i>in vitro</i> mutagenicity <input type="checkbox"/> Sub acute toxicity (28 days) <input type="checkbox"/> Reproductive toxicity screen 	<ul style="list-style-type: none"> <input type="checkbox"/> Acute aquatic toxicity – Fish <input type="checkbox"/> Activated sludge <input type="checkbox"/> Adsorption/desorption screening
100- 1000t	<ul style="list-style-type: none"> <input type="checkbox"/> Further mutagenicity tests <input type="checkbox"/> Sub-chronic toxicity (90-days) <input type="checkbox"/> Further reproductive toxicity tests 	<ul style="list-style-type: none"> <input type="checkbox"/> Long term aquatic toxicity daphnia and fish <input type="checkbox"/> Further degradation and fate/behaviour studies <input type="checkbox"/> Short term effects on terrestrial organisms
>1000t	<ul style="list-style-type: none"> <input type="checkbox"/> Further mutagenicity tests <input type="checkbox"/> Carcinogenicity <input type="checkbox"/> Chronic toxicity <input type="checkbox"/> Further reproductive toxicity tests 	<ul style="list-style-type: none"> <input type="checkbox"/> Further degradation and fate/behaviour studies <input type="checkbox"/> Long term effects on terrestrial organisms



Registration – OSOR

Joint information	Hazard information and testing proposals Classification and labelling
Individual information	Company specific information Information to keep confidential
Choice	CSR Guidance on safe use Quality assessed

- Joint data submission: mandatory with opt outs:
 - Disproportionate cost
 - Commercial secrets
 - Disagreement on selecting data



Registration – Substances in Articles

Registration of substances intentionally released

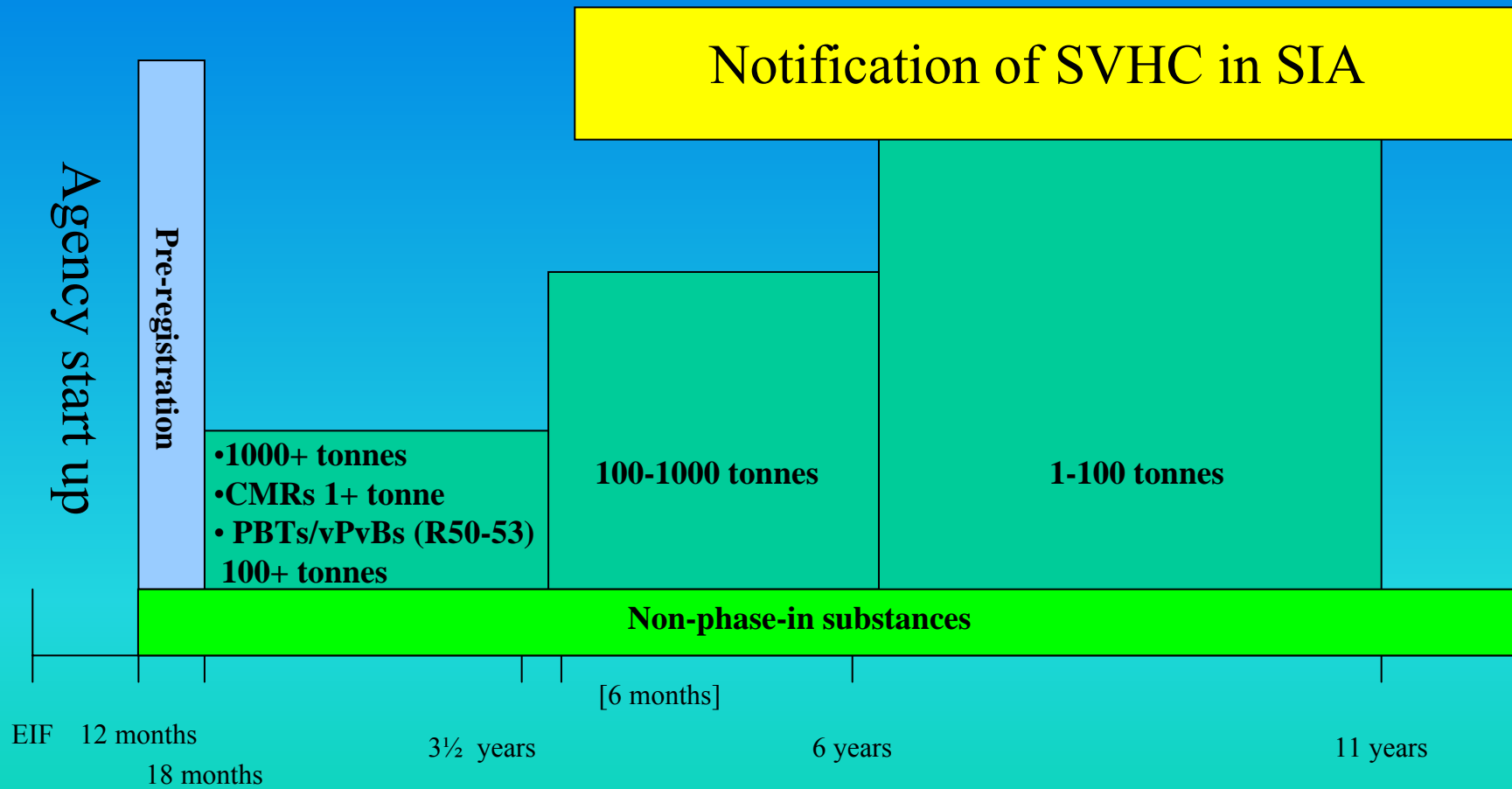
- Substance present above 1 tonne
- Agency may require registration for substances which are not intentionally released from an article but present a risk.

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.



Registration Timeline





Availability of Information

Published on web, free of charge:

- Information on substance identity,
- classification,
- physicochemical data,
- results of toxicological and ecotoxicological studies,
- DNELs, PNECs,
- guidance on safe use,
- analytical methods.

Published on web, free of charge, unless companies justify otherwise:

- Information on tonnage bands,
- impurities,
- information in the SDS (unless above),
- study summaries/robust study summaries,
- IUPAC name / trade name (for new dangerous substances up to 6 years).



Evaluation

Provide confidence that industry is meeting obligations
Prevent unnecessary testing

Dossier evaluation: Agency



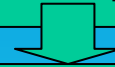
Check test proposals



Compliance



Substance evaluation:
Agency (MS)



Examine any information on
a substance on CRP



Output:

- Further information decisions
- Info to other parts of REACH/other legislation



Authorization

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

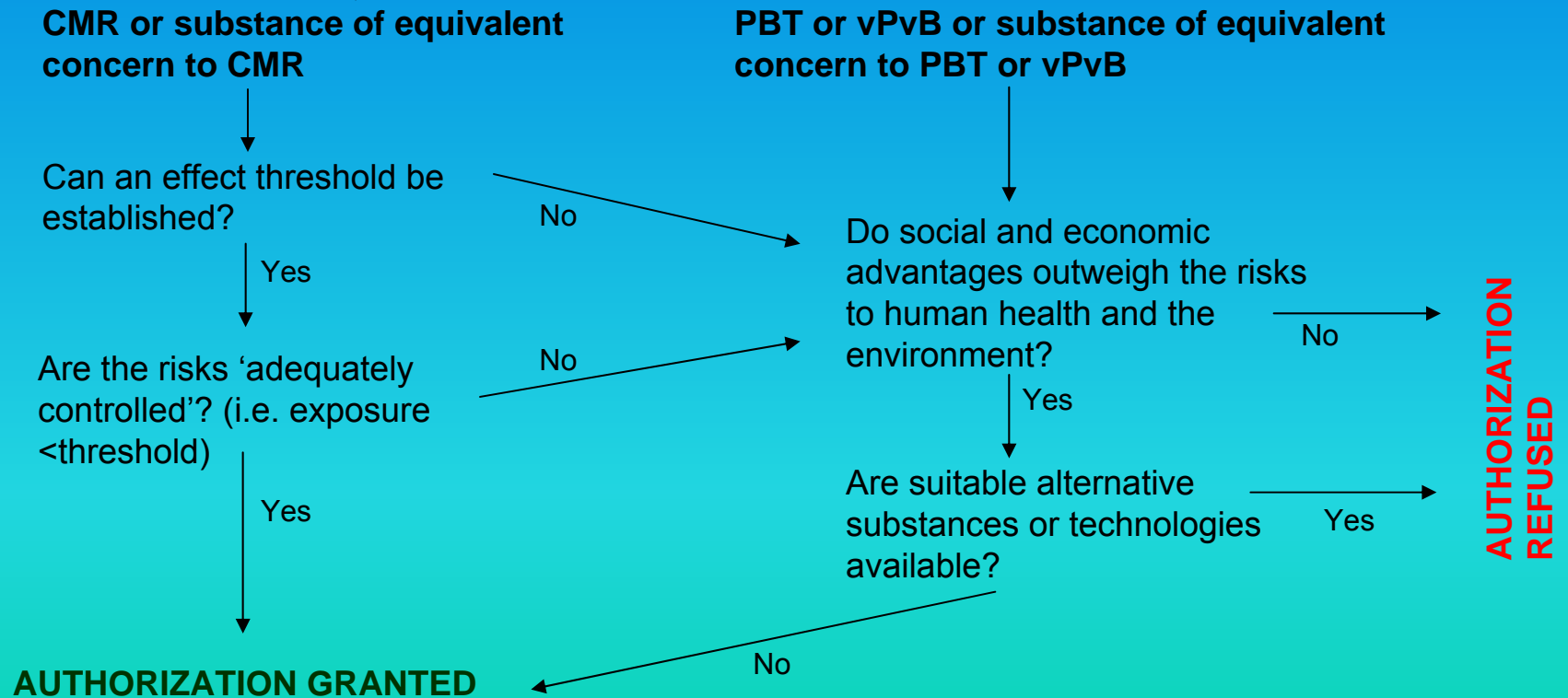
- ❑ Substances of very high concern:
 - Carcinogenic, mutagenic, reprotoxic (CMR)
 - Persistent, bioaccumulative and toxic (PBT)
 - Very persistent and very bioaccumulative (vPvB)
 - Substances of “equivalent concern for which there is scientific evidence of probable serious effects”



Authorization Chart

SUBSTANCES OF VERY HIGH CONCERN CMR CAT.1&2, PBT, vPvB

+ substances 'for which there is scientific evidence of probable serious effects to humans or the environment which give rise to an equivalent level of concern'





Restrictions

Objective: act as safety net

- Community wide concern
- MS/COM initiated
 - Fast track possible e.g. CMR substances for consumers.
- Agency Committees examine:
 - The risk, and
 - The socio-economic aspects involved.
- Commission - final decision through comitology
- Carry-over of existing restrictions (76/769/EEC).



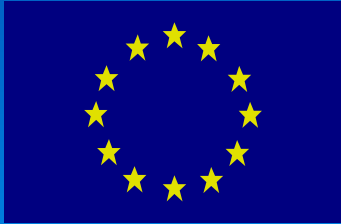
European Chemicals Agency

Day to day management of REACH

- Technical, scientific and administrative aspects

Responsibilities:

- Registration - reject or require completion of registration
- Evaluation - carry out dossier evaluation, responsible for substance evaluation, ensure a harmonised approach; take decisions
- Authorization/restrictions - facilitate process; suggest priorities
- Secretariat for Forum and Committees
- Deal with appeals - registration, R&D, evaluation, confidentiality.



Next: REACH Implementation

- End 2006* – *Publication in the Official Journal*
- June 2007 – Entry into force of REACH
 - Setting up the Agency in Helsinki
- June 2008 – Agency operational
- June – November 2008 – Window for **Pre-Registrations**
- June 2010 – First substances prioritized for **authorization**
- June 2010 – ‘New’ **restrictions**
- End 2010 – First **registration** deadline for >1000t &CMR
- End 2018 – **Last** registration deadline for >1t



The Interim Strategy

4 basic work elements:

- Re-focus Current Activities
- Preparing for REACH
- Strategic Partnerships
- Setting up the Agency

Aligning Dir. 67/548 and Reg. 793/93 with REACH

Developing Guidance Documents and Software Tools for efficient, transparent and consistent implementation

“Working together, preparing for REACH”

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



3.1: Preparing the registration dossier

3.2: Preparing the CSR

3.10: Guidance on checking substance ID

3.3: Information requirements

3.4: Guidance on data-sharing

RIP-3

3.5: Guidance for downstream users

3.7: Guidance on applications for authorization

3.8: Requirements for articles

3.9: Guidance on SEA

3.6: Guidance on C&L under GHS



4.1: Guidance on dossier evaluation

4.2: Guidance on substance evaluation

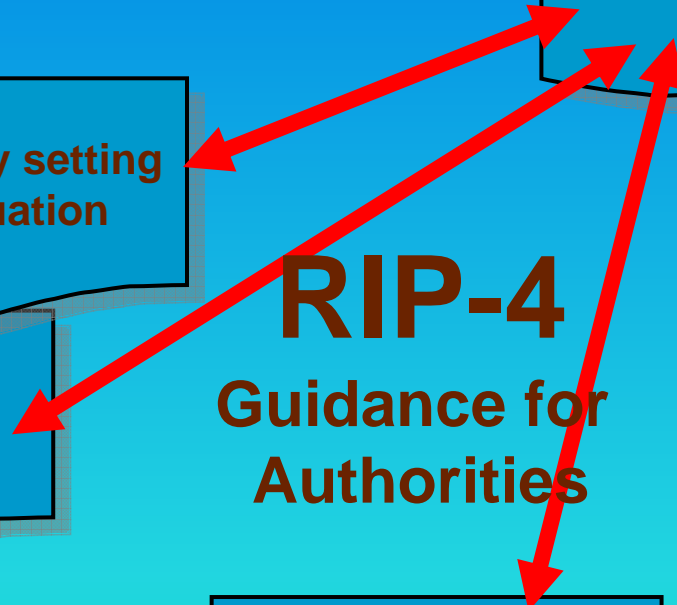
4.5: Priority setting for evaluation

4.3: Inclusion of substances in Annex XIII

RIP-4

Guidance for Authorities

4.4: Preparation of Annex XIV dossiers





Guidance for Industry & Authorities

□ RIP 3/4:

- Preparing a Chemical Safety Report *
- Information Requirements *
- Data-sharing (Pre-registration)
- Downstream user Requirements*
- Carrying out a Socio-Economic Analysis*
- Preparing an Application Dossier for Authorization
- C&L under GHS
- Preparing the Technical Dossier for Registration
- Priority Setting for Evaluation
- Dossier Evaluation
- Substance Evaluation
- Inclusion of Substances into the list of substances subject to Authorisation

* Definitive document



Stakeholder Expert Groups

- Discuss the project implementation, including work plan, deliverables and timing
- Discuss progress and advise on consequent adjustments needed to the work plan
- Provide comments on draft guidance documents
- Where relevant, and a mandate has been given by the Commission, carry out parts of the RIP work.



SEG Representation

- ❑ Approximately 200 experts follow the process!
- ❑ 19 Member States or accession countries
- ❑ Industry organisations:
 - CEFIC, CEPE, CEPI, CONCAWE, DUCC, ESIA, Euratex, Reach Alliance, EuPC, BLIC, EDANA, Eurocommerce, AISE, ASD, FECC, UNICE, ESBA, CIA, EPIA
- ❑ NGO's:
 - ETUC, FoE, WWF, ECEAE, EEB, Greenpeace
- ❑ Others:
 - OECD secretariat, Health Canada, Japan Business Council in Europe



Example: Exposure Scenarios in RIP

3.2

- ❑ Exposure Scenarios represent a new element of “risk assessment” and is central to REACH implementation;
- ❑ Industry, in particular sector / branch organisations should provide support by gathering best practice Risk Management Measures and developing generic but sector-specific Exposure Scenarios



The 'Arona network'

Main conclusions

1. A manageable number of ES is needed to cover standard processes within an industrial sector
2. Bottom-up approach is a way forward in developing ES
3. Use standard descriptions of current practice within industrial sectors as a starting point


Report and presentations at: <http://ecb.jrc.it/REACH>

→ documents → Arona network



Further information on RIPs

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

REACH (Registration, Evaluation and Authorisation of CHemicals) 

HOME DOCUMENTS CALLS FOR TENDER REACH PROPOSAL RIP PROJECTS STRATEGIC PARTNERSHIPS USEFUL LINKS

Biocides
Classification & Labelling
Existing Chemicals
Export-Import
New Chemicals
Testing Methods
QSARs
REACH
ESIS
INFOCAP
Contacts
Documents
Legislation

A proposal on a new EU regulatory framework for Registration, Evaluation and Authorisation of Chemicals (REACH) was adopted 29 October 2003. REACH aims to improve the protection of human health and the environment while maintaining the competitiveness and enhancing the innovative capability of the EU chemicals industry. ECB has the responsibility of developing methodologies, tools and technical guidance needed for REACH through a number of REACH Implementation Projects (RIPs). This is managed under Action no 1313 - Support to future chemicals legislation (REACH) or in short *REACH Support*.

Contact Person - Action Leader: [Jack de Bruijn](#)

Overview

On 27 February 2001 the Commission issued a White Paper on a Strategy for a future Chemicals Policy. This has subsequently been developed and extensively discussed with major stakeholders, resulting in the release on 29th Oct 2003 of the Commission's proposal (REACH).

Under REACH enterprises that manufacture or import more than one tonne of a chemical substance per year would be required to register it in a central database. REACH would furthermore give greater responsibility to industry to manage the risks from chemicals and to provide users in the supply chain with safety information on the substances.

The proposal is now being considered by the European Parliament and the Council of the EU for adoption under the so-called co-decision procedure.



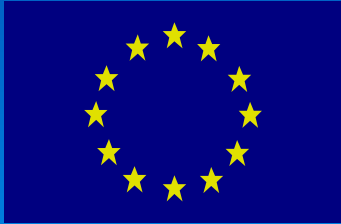
Interplay US and EU legislation (1)

- ❑ The EU and the US face similar issues: limited attention for existing chemicals – based on voluntary and/or regulatory initiatives and data collection on a limited number of chemicals, with little focus on information on uses (= risks), hence risk management and restrictions; and high regulatory focus on new chemicals which only represent a very small fraction of chemicals in commerce.
- ❑ There are some positive aspects of the U.S. system that could help the performance of REACH such as the use of modeling ((Q) SARs) and grouping of chemicals, and experience with and rules for R&D, polymers, Low volume, Low Release and Exposure



Interplay US and EU legislation (2)

- ❑ In turn, policy wise, REACH will probably provide an important driver to an overhaul of the US system and further chemicals testing and management, starting at state level (California, Massachusetts), but probably surfacing at the federal level in the near future.
- ❑ REACH also will provide lots of data on properties on HPVs and in due course on lower tonnage chemicals, chemical use information, exposure scenarios, validated computer models and in vitro testing on certain end points, which will help risk assessment in the EU, the US and elsewhere.



Preparation by stakeholders

- Inventarize your substances and uses
- Study guidance developed:
 - <http://ecb.jrc.it/REACH/>
- Develop exposure scenarios
- Communicate in the supply chain
 - Develop partnerships
 - Discuss how to meet their needs and yours
- Plan for the future
 - Don't leave data generation and assessment too late



E U R O P A

Thank you!

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

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