REACH

What does it mean and how can you prepare?

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TYPES OF LEGISLATIVE MEASURES USED IN EU ENVIRONMENT POLICY

- Directives: indirectly legally binding for Member States, setting objectives, to be transposed in national law (because of mixed competence, most used instrument for EU environment policy)
- Regulations: directly legally binding for Member states in all its details, no need to transpose (in EU environment policy mainly used for transposition of international treaties, but …REACH)
- Decisions: directly legally binding to the addressee (s) (used for ozone depletion substances allocations for critical uses)
- Recommendations, guidance documents: not legally binding (used for agreements on car emissions with Korean, Japanese car manufacturers)

The Current EU Chemicals Policy

Problems

- Distinction between new and existing substances, September 1981
- New substances heavily regulated, 0.01 % of marketed volume
- Existing substances virtually not regulated, 99.9 % of marketed volume

Burden of the Past

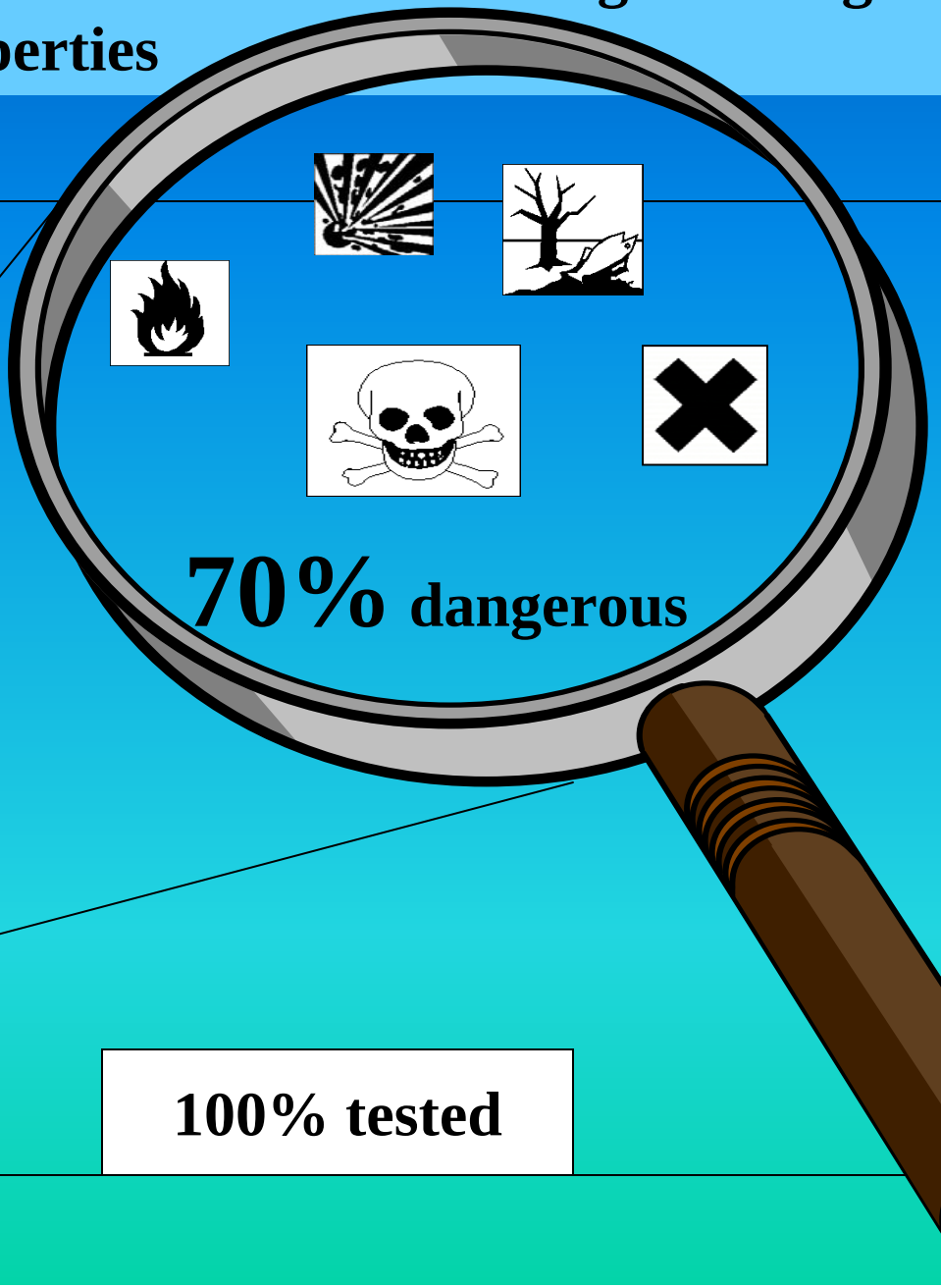
The Current EU Chemicals Policy

Existing substances

- Existing substances can be used without testing (100,106 existing substances registered in EINECS)
- 30,000 to 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: few substances assessed
- Insufficient resources on the part of Member States: heavy delays (4 to 6 years for some substances)

Lack of Confidence in Chemicals

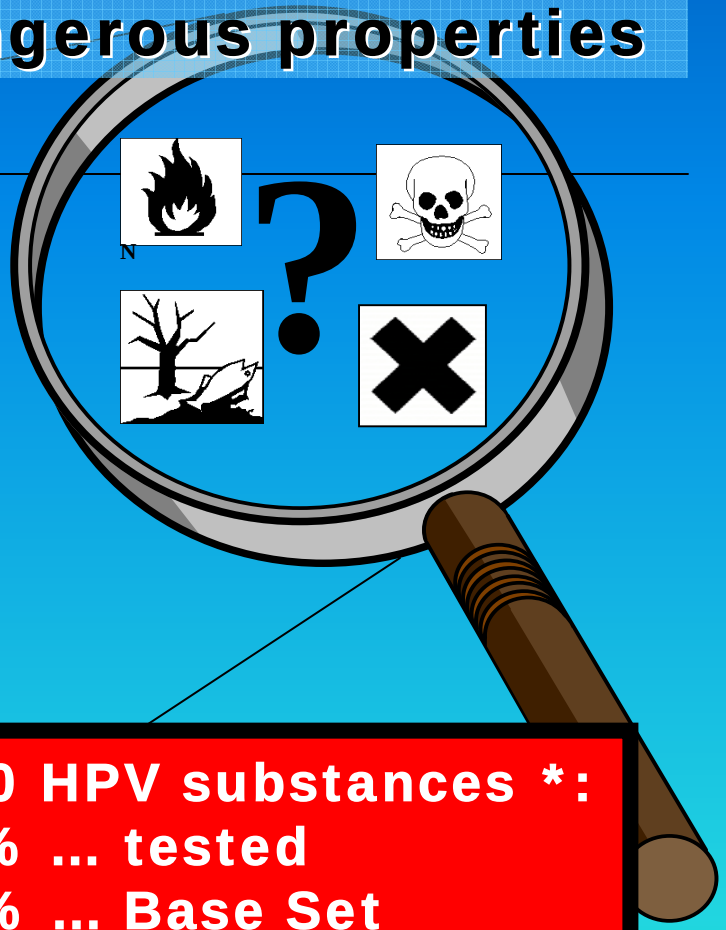
New substances - Knowledge of dangerous properties



3.500
new substances

100% tested

Existing substances
Knowledge of dangerous properties



30,000
existing substances

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

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

A careful approach

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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 to WTO obligations

Substitution and precaution underpin system

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.

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WHAT is REACH? (1)

- Proposal for a Regulation on the **R**egistration, **E**valuation and the **A**uthorisation of **CH**emicals
- Scope:

  manufacture, import, placing on market and use of substances (on their own, in preparations or in articles)
- Goals:
  - Improving health and safety of workers and the general public.
  - Environmental protection – avoiding chemical contamination of air, water, soil and damage to biodiversity
  - Maintaining a competitive/innovative chemicals industry

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WHAT is REACH? (2)

- Registration of substances ≥ 1 metric tonne/yr
- Increased information and communication throughout the supply chain
- Evaluation of some substances: testing proposals
- 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!

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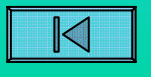
REACH: Registration

Objective: Ensure industry adequately manages risks from substances

- **Method**:
  - Manufacturer/Importer obtains/generates adequate information
  - Electronic dossier submitted to Agency
  - Non-confidential information to central (largely public) database.
- **Scope**
  - Substances Manufactured/Imported ≥ 1 metric tonne/year; no threshold for authorization substances
  - Exemptions: other law, Annex II/III; polymers (review); PPORD
  - As registered: biocides, pesticides, notified substances.
- **Consortia encouraged**

Industry's responsibility



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Registration (3): OSOR

ONE SUBSTANCE ONE REGISTRATION

- **Pre-registration of all substances**

  18 (12?) months after Entry into Force

- **Data sharing**
  - Animal data always shared
  - Non animal data shared on request
- **Joint data submission: mandatory with opt outs:**
  - Disproportionate cost
  - Commercial secrets
  - Disagreement on selecting data

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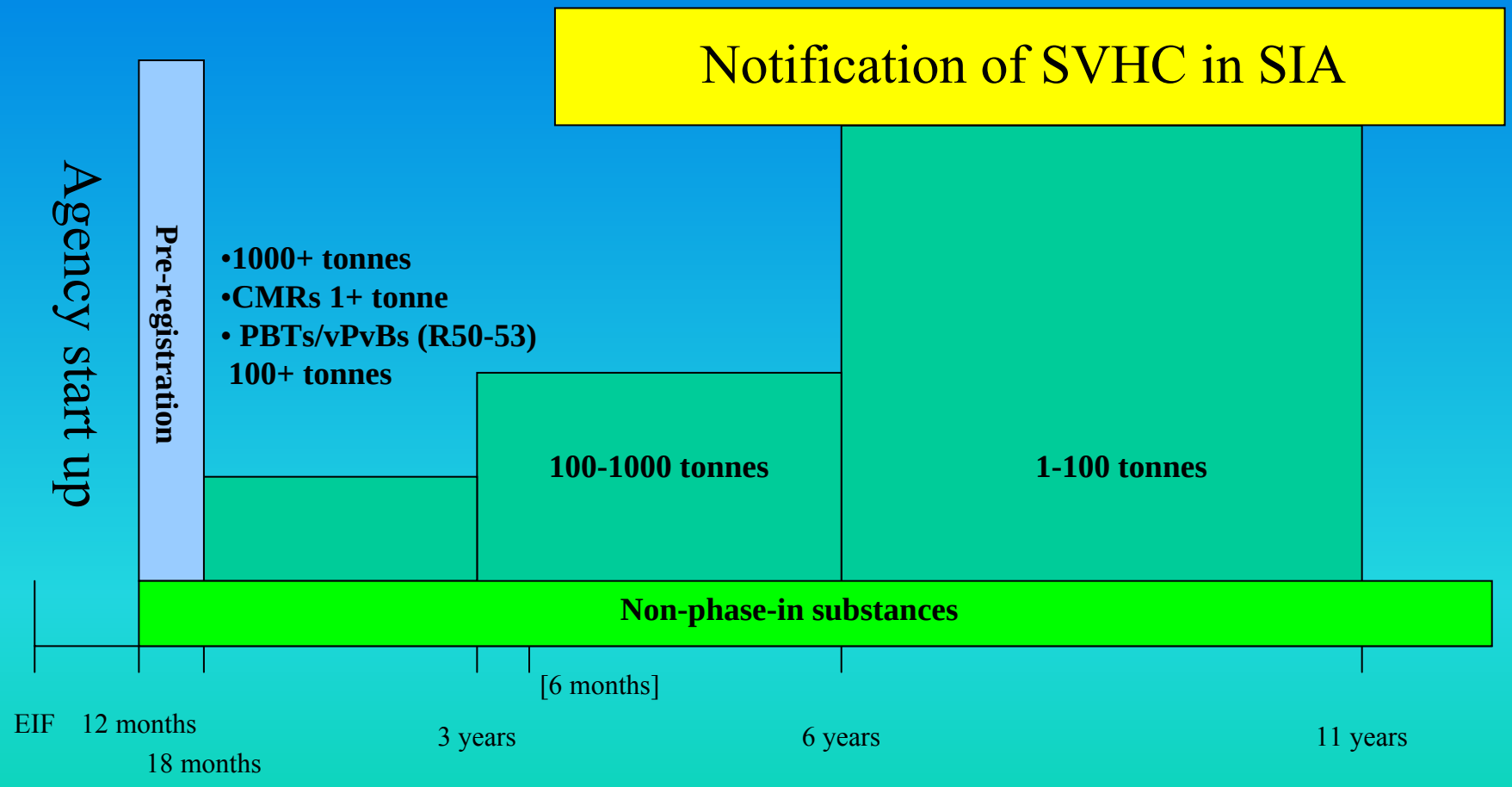
REACH: Registration (2)



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Registration: Substances in articles (SIA) (1)

- **Registration of substances <u>intentionally released</u> (Art. 6.1)**
  - applies to all SIA (i.e. no requirement to meet criteria for classification as dangerous)
  - deadlines as other substances

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Registration: Substances in articles (SIA) (2)

- Notification of substances of very high concern (Art. 6.2) if:
  - present above a concentration limit of 0,1%,
  - exposure of the public or the environment during the full life cycle cannot be excluded,
  - it is present above 1 tonne
- applies 6 months after substance listed on authorization candidate list – i.e. only commences 3 years and 6 months after EIF

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Registration: Substances in articles (SIA) (3)

- Agency can request registration of any notified substance contained in articles, when:
  - Substance is present over 1t; AND
  - Suspects that the substance is released and that release presents a risk to human health or the environment; AND
  - Substance is not subject to Art. 6.1

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REACH: Authorization

Objective: Ensure risks from substances of very high concern (SVHC) are properly controlled and eventually substituted.

- **Applies to**
  - SVHC (CMR, PBT, vPvB, 'serious and irreversible effects')
  - Substance, substance in mixture (unless below concentration limit), substance incorporated into an article
- Substance **cannot be used unless authorized**
- **Prioritized** - Substances progressively authorized (as resources allow)
- **Downstream Users** can use suppliers authorization.
- **Commission** grants authorizations on proposal of Chemicals Agency

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Authorization (2)

- **Criteria for granting authorizations:**
  - Authorization granted if adequate control
    - ➔ Not available for PBT, vPvBs or CMRs/substances of equivalent concern if not possible to determine a threshold.
  - Still possible to grant authorization if socio-economic benefits outweigh the costs
  - Analysis of substitutes in all cases.
- **Public list of substances to be authorized (eventually):**
  - Published by Agency
  - Candidate list: substances meeting criteria
  - Annex XIII (substances prioritized and picked for authorization within set timeframe)

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Evaluation

Provide confidence that industry is meeting obligations

Prevent unnecessary testing

Dossier evaluation

Check test proposals

Compliance

Substance evaluation

Examine any information on a substance on CRP

Output:

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

REACH: Restrictions

Objective: act as safety net

- Community wide concern
- Member States/Commission 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 Commission's responsibility

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European Chemicals Agency

- Day to day management of REACH
  - Technical, scientific and administrative aspects
- Responsibilities:
  - Registration - reject or require completion of registration
  - Evaluation - ensure a harmonised approach; take decisions
  - Authorisation/restrictions - facilitate process; suggest priorities
  - Secretariat for Forum and Committees
  - Deal with appeals - registration, R&D, evaluation, confidentiality.

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Progress in co-decision

Parliament: First reading: 17 November 2005

Council: Common Position by unanimity: 27 June 2006

- In 2006
  - 2nd reading in Parliament (End of November 2006)
    - Authorization regime
    - Substitution
  - Council of Ministers Meeting (11-12 December 2006)
  - Council and Parliament Agreement end of 2006?
- 2007 Entry into force (estimated April/May 2007)
- 2008 Agency commences
- **2010 First Registration deadline (1000 tonnes +)**

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REACH and GHS

- Currently, EU classification and labelling requirements included in the Dangerous Substances Directive, the Dangerous Preparations Directive and the Safety Data Sheet Directive
- August 21, 2006, the European Commission launched a 2 month internet consultation on a draft legislative proposal to introduce GHS
- Final Commission proposal by end of 2006/beginning of 2007 will include transitional arrangements
- Entry into force around the same time as entry into force of REACH

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The Interim Strategy

The interim strategy has 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

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Preparing for REACH

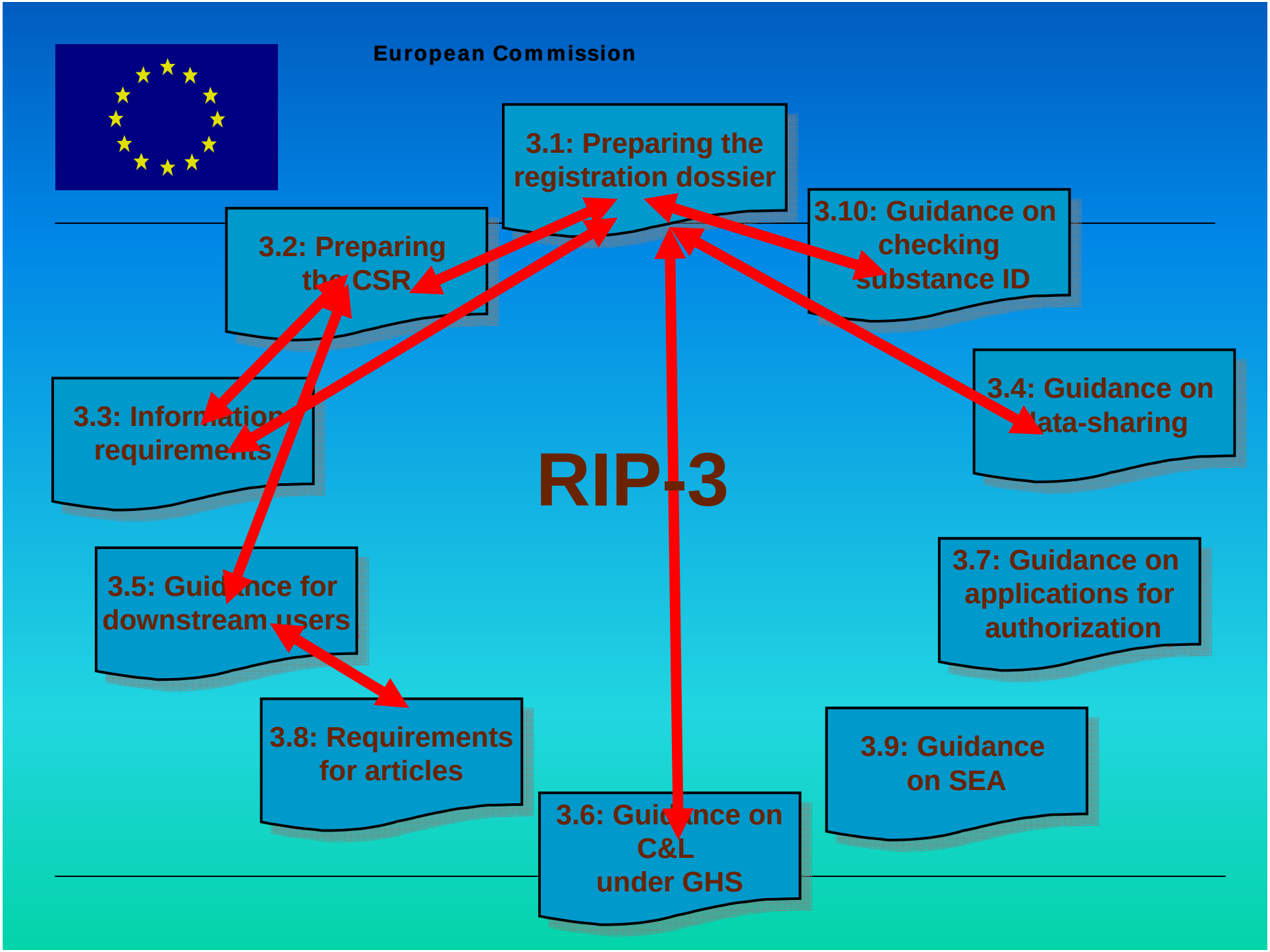
REACH Implementation Projects (RIPs):

- RIP 1: Process descriptions
- RIP 2: Development of IT systems (IUCLID database and REACH-IT)
- RIP 3/4: Guidance Documents industry/authorities
- RIP 5/6: Setting up the (pre-) Agency

Objective: In close collaboration with all stakeholders develop guidance to help fulfil the obligations under REACH

RIP-2: REACH-IT and IUCLID-5

- 2 main systems, “talking to each other”
  - IUCLID 5:
    - Industry: tool for capturing data on chemicals, preparing and submitting dossiers
    - Agency and Member States: central data repository for all dossiers submitted and tool for preparing different kinds of evaluation dossiers
  - REACH-IT:
    - Support for managing the complete system
    - Agency web portal
    - Workflow system
    - Dissemination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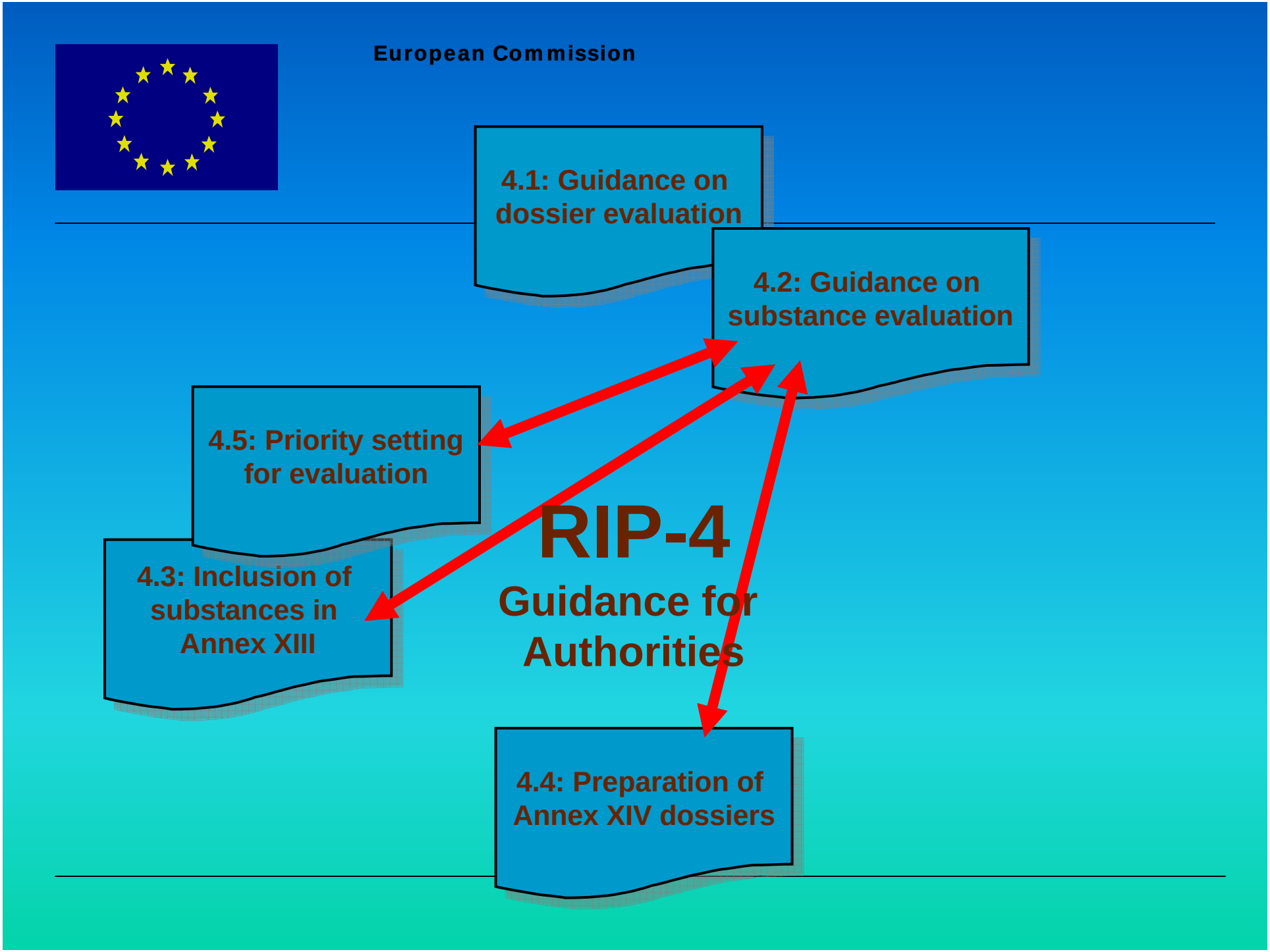
3.1: Preparing the registration dossier
3.2: Preparing the CSR
3.10: Guidance on checking substance ID
3.3: Information requirements
3.4: Guidance on data-sharing
RIP-3
3.5: Guidance for downstream users
3.7: Guidance on applications for authorization
3.8: Requirements for articles
3.9: Guidance on SEA
3.6: Guidance on C&L under GHS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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

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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

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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

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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

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Preparation: U.S. exporters

- REACH may have implications for your business - costs, professional resources, R&D, portfolios of chemicals, procurement, relations up and down the supply chain, management systems etc.
- It is important to have a clear and realistic understanding of the implications of REACH
- Make an Inventory of substances to be exported
- Study obligations of your EU importer
  - REACH registration requirements
  - Guidance developed: http://ecb.jrc.it/REACH
- Actively communicate with your EU clients to see how their needs can be met and
  - Provide adequate information on the substances
  - Develop and provide exposure scenarios
- Plan for the future
  - Don’t leave data generation and assessment too late

Conclusions

- REACH is on the horizon and expect agreement by the end of the year.
- REACH Implementation Projects being prepared and ready by mid-2007. Consult drafts and give input!
- REACH opportunity to rebuild confidence in chemicals
- Start preparing your company now and understand the implications of REACH for your business

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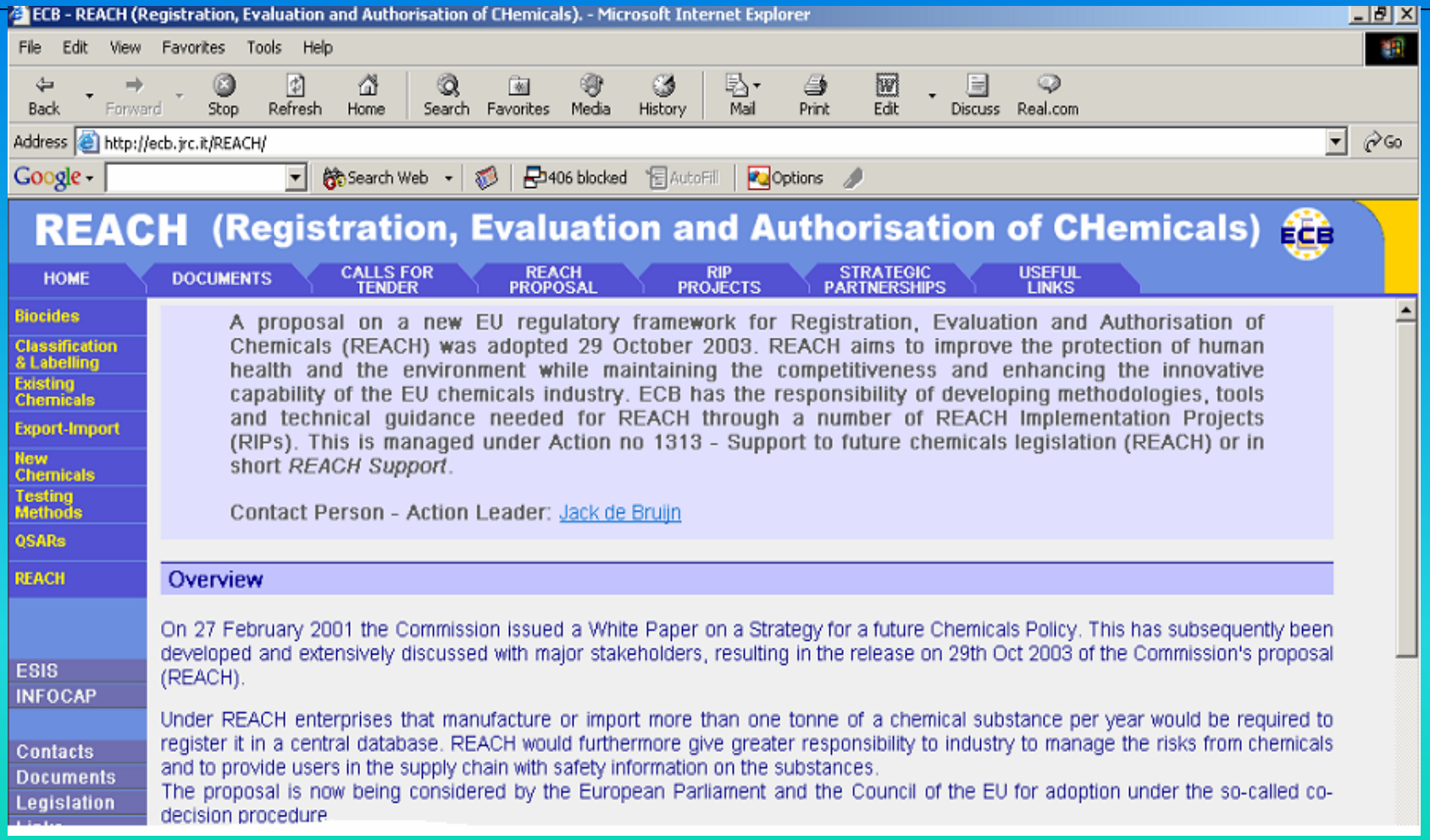
Further information on RIPs

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



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Information

EUROPA

Thank you!

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

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