



The REACH Implementation Projects, Overview of their contents, management and stakeholder involvement

Jack de Bruijn

European Commission, DG JRC
Institute for Health and Consumer Protection (IHCP)
European Chemicals Bureau (ECB)

Workshop on REACH Implementation Project 3

25 September 2006, Brussels





REACH Implementation Projects



- Why RIPs
- What do they cover ?
- How are they set up and managed ?
- How are stakeholders involved ?
- Where we are and where do we go ?



Why RIPs

- REACH is a comprehensive piece of legislation covering a wide range of aspects of chemicals management
- Guidance and support tools are essential to help stakeholders understand their tasks and fulfil their obligations
- Successful implementation needs proper and timely preparation

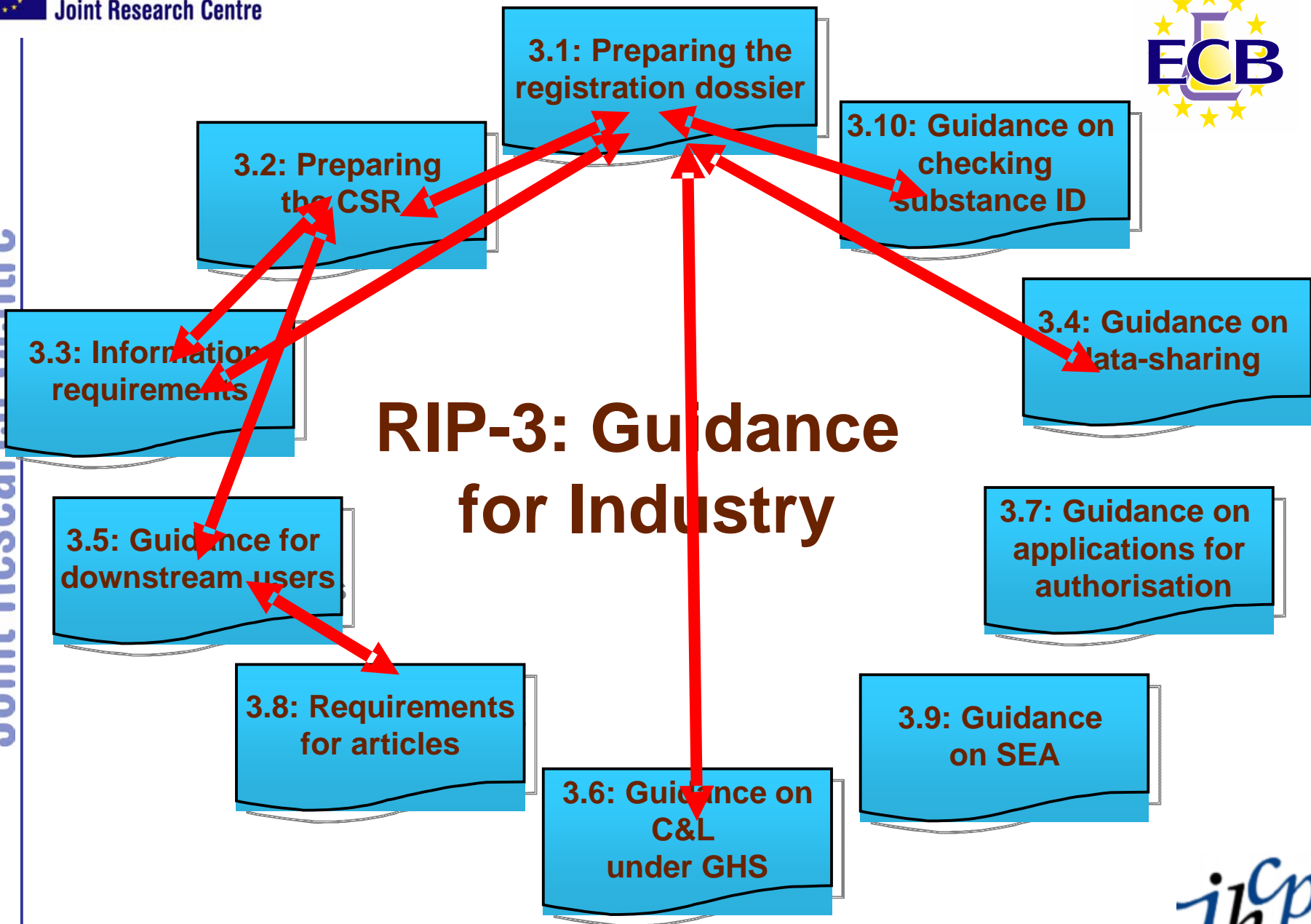
Start 2003

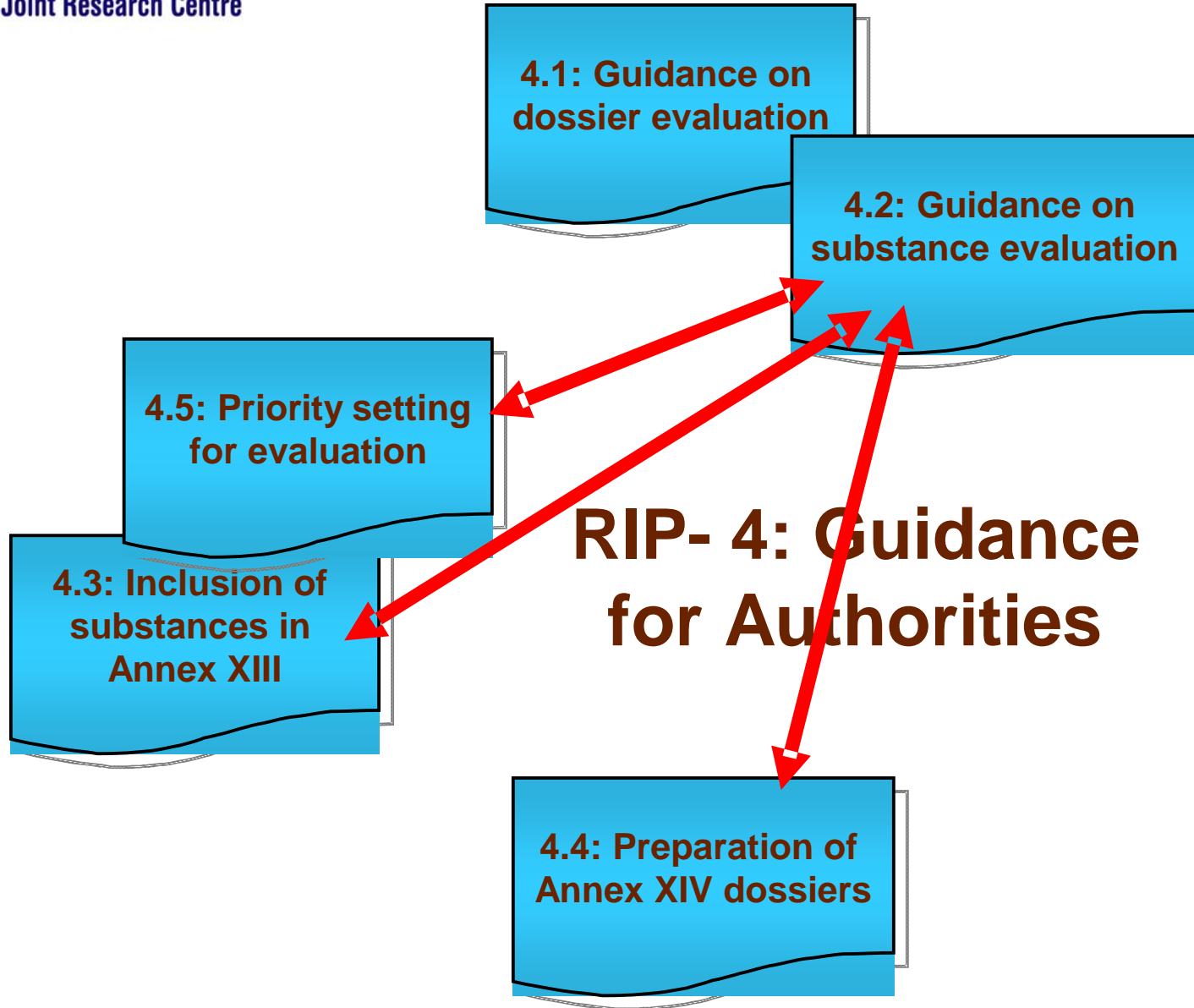
Preparations for REACH: Commission Interim Strategy

REACH Implementation Projects (RIPs):

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

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





TGD* on preparing a chemical safety report (RIP 3.2)

Objective:

Develop guidance on how to prepare a Chemical Safety Assessment (CSA) and document it in the Chemical Safety Report (CSR)

- Overall workflow – CSA, CSR, SDS
- Further development of the exposure scenario (ES) concept
- How to incorporate ESs into SDSs ?
- Targeting the chemical safety assessment
- Tools and methodologies for SMEs
- Use current TGDs as a basis, new elements added!

- Scoping report available: Final guidance under preparation

TGD on Information requirements under REACH (RIP 3.3)

Objective:

Guidance for industry on:

- how they can fulfil the information requirements on intrinsic properties (Annexes VI to X) and
- how to use alternative information for decision-making under REACH on C&L, PBT assessment and Chemical Safety Assessments (Annex XI)
- Intelligent/Integrated testing strategies
- Scoping report available: Final guidance under preparation

Guidance for Downstream Users (RIP 3.5)

Objective:

Develop guidance for DU on how they can fulfil their obligations:

- Use of chemicals and exposure scenarios
- Which information shall be available
- Communication up- and downstream

Take account of different DU roles: users of chemicals, formulators, producers incorporating substances/preparations into articles, etc.

- Scoping report available: Final guidance under preparation



Identification and Naming of Substances in REACH (RIP 3.10)

Objective:

Develop guidance for manufacturers and importers (M/I) on how to characterise and record the identity of a substance

- Rule base for Substance ID
- Stepwise approach on how to identify and record the identity of a substance
- Workflows on how industry can and should check substance identity before and during pre-registration and registration
- Guidance on how to deal with natural substances, reaction mixtures and UVCBs
- Draft final guidance available



TGD on Data Sharing (RIP 3.4)

Objective:

Provide guidance for industry on data sharing within REACH

- Process descriptions for data sharing for phase-in and non-phase-in substances
- Analyse technical hurdles to data sharing and provide solutions
- Guidance on the procedural aspects of data sharing taking into account issues related to costs, EU competition law and confidential business information (CBI)
- Guidance on working procedures in a SIEF, including consortium formation



How are the RIPs set up and managed ?



General management of the RIPs

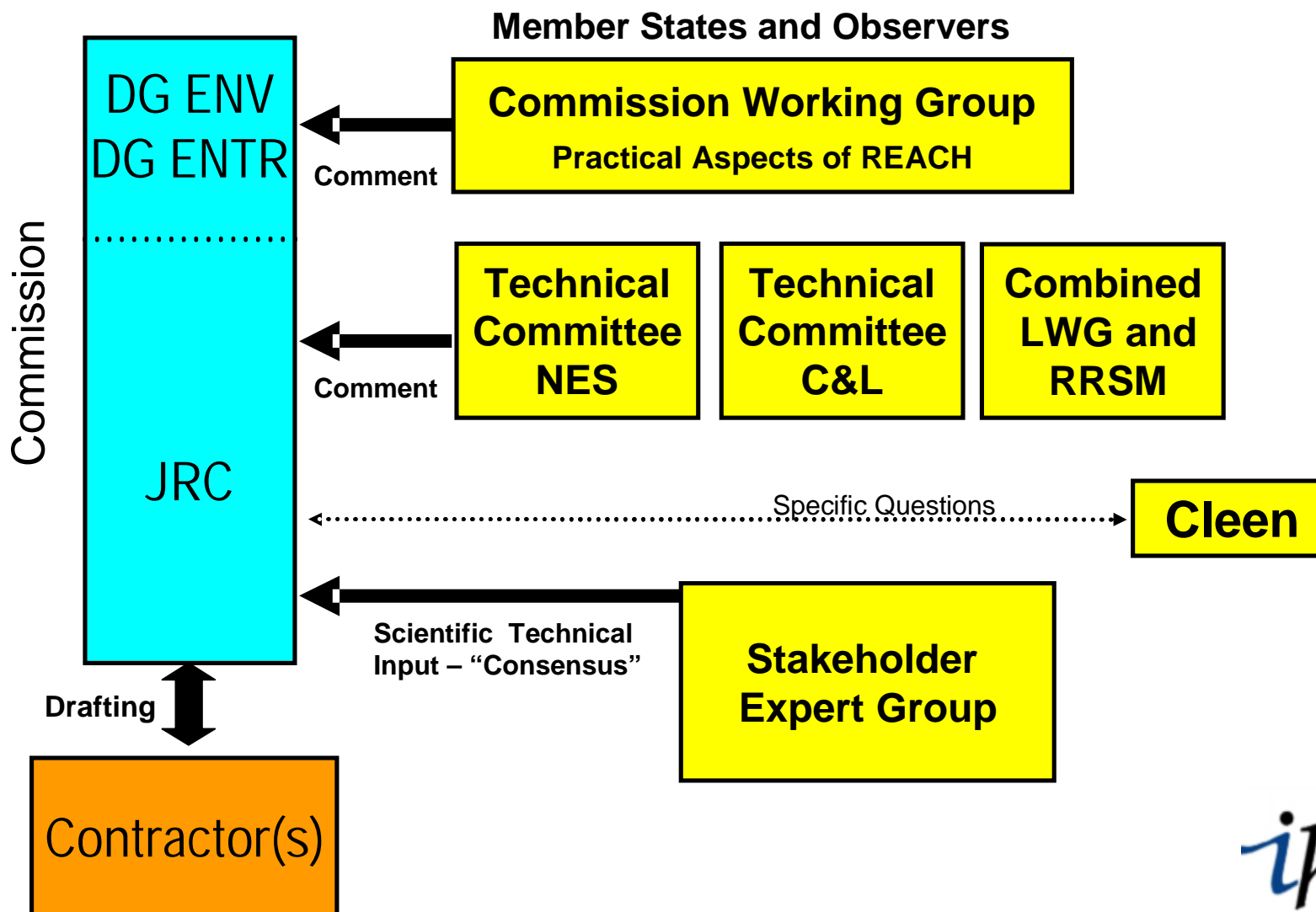
- Overall process coordinated by the European Chemicals Bureau (ECB) of the JRC
- Most projects are tendered out via open call for tenders
- A number of projects have started with scoping studies
- Working papers and draft final reports are being discussed in Stakeholder Expert Group (SEG) meetings
- Industry, Member States, NGOs and the Commission take part in the SEG meetings and provide input and written comments
- Final reports are being discussed and commented by the Technical Committees following today's chemicals legislation

Under REACH, the Agency will be responsible for the guidance!



Organisational Diagram

Joint Research Centre



Stakeholder Expert Group participation

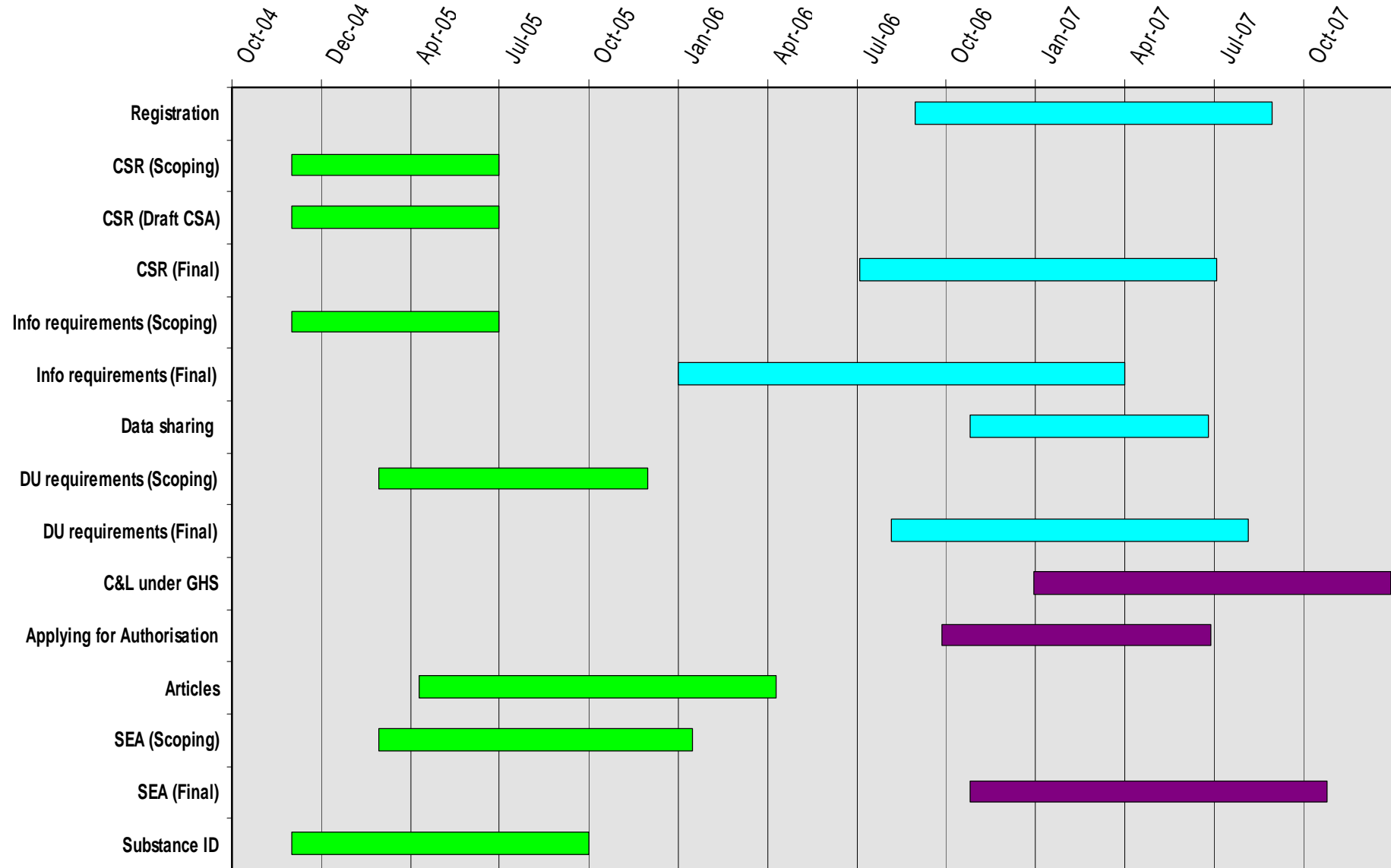
- Nomination of experts via Commission Working Group on REACH (Members + Observers)
- More than 200 experts follow the process!
- 19 MS or accession countries
- Many Industry organisations:
 - CEFIC, CEPE, CEPI, CONCAWE, DUCC, ESIA, Euratex, Reach Alliance, EuPC, BLIC, EDANA, Eurocommerce, AISE, ASD, FECC, UNICE, ESBA, CIA, EPIA, VCH, 3M
- Many NGO's:
 - ETUC, FoE, WWF, ECEAE, BUAV, EEB, Greenpeace
- Others:
 - OECD, US-EPA, Health Canada, Japan Business Council in Europe



Where we are and where do we go ?



Timelines for RIP 3 projects



Project deliverables (1)

- 8 Projects finalised:
 - RIP 3.2-1A: TGD on preparing the CSR (Scoping)
 - RIP 3.2-1B: TGD on preparing the CSR (Draft CSA)
 - RIP 3.3-1: TGD on information requirements (Scoping)
 - RIP 3.5-1: TGD on Downstream User requirements, preliminary study
 - RIP 3.9-1: Preliminary study on Socio-Economic Analysis

 - ü RIP 3.8: Guidance on fulfilling the requirements for articles
 - ü RIP 3.10: TGD on Identification and Naming of Substances in REACH
 - ü RIP 4.4: TGD on the preparation of Annex XV dossiers

- 5 Projects running
 - RIP 3.2-2: TGD on preparing the CSR
 - RIP 3.3-2: TGD on information requirements
 - RIP 4.1/4.2 Guidance on Dossier/Substance evaluation
 - RIP 3.5-2: TGD on Downstream User requirements
 - RIP 3.1: Guidance on Registration

Project deliverables (2)



- 4 Projects to start:
 - RIP 3.4: TGD on data sharing (Oct 2006)
 - RIP 3.6: Guidance on Classification and Labelling under GHS (Jan 2007)
 - RIP 3.7: Guidance on preparing an Authorisation Application (Nov 2006)
 - RIP 3.9-2: Guidance on carrying out a Socio-Economic Analysis (Oct 2006)



The overall guidance package

Objective:

- to make the extensive guidance for REACH available in a way that allows stakeholders to quickly find and retrieve the guidance they need for understanding and fulfilling their obligations under REACH
- Overall guidance:
 - Should be concise
 - Contain 'non-technical' information
 - Serve as introduction to the more detailed guidance
- Web application; available at Entry into Force

Framework for the overall guidance package

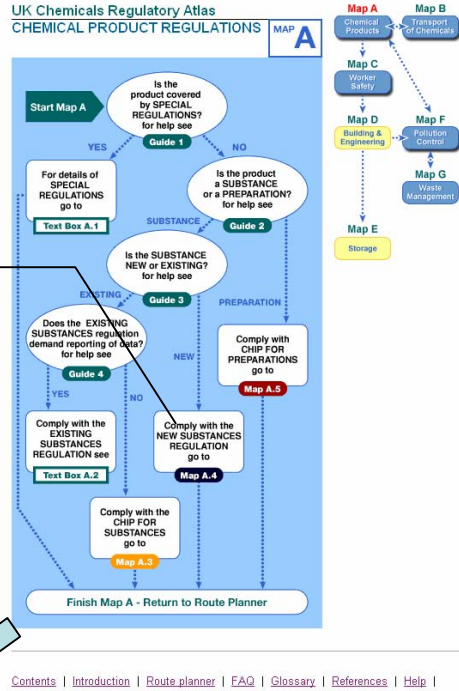
REACH Overall Guidance Start Page(s)
Example: <http://www.prc.cnrs-gif.fr/reach/anglais/home.htm>

Guidance Navigator

The screenshot shows a web browser window with a navigation menu. At the top, there are buttons for 'Chemicals covered', 'Data on chemicals', 'Tools', and 'Players'. Below these are sub-buttons for 'Classification', 'Safety data sheet', 'Chemical safety sheet', 'Substances', 'Information', and 'Restrictions'. A 'Search Engine' box is on the left. The main content area is titled 'Tools' and contains text about REACH legislation, the ECHA website, and various regulatory tools like classification, labeling, and restrictions. A 'Language buttons' callout points to the top navigation area. A 'Guidance Navigator' callout points to the 'Tools' section. An 'Overview of available Guidance Documents' callout points to the main content area.

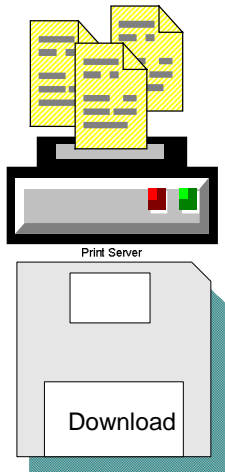
1-1.5 page (simple) introductions to REACH processes and tools (with links to more detailed guidance)

Objective is to help Industry to figure out their obligations and to guide them to the relevant parts of the guidance, tools and formats in order to fulfill these obligations



Detailed guidance documents (steps and methods)

- 5-10 page summaries
- Links to other guidances
- Links to formats





Main elements

1. Start page(s)
 - General information on REACH
 - Summarize REACH processes (Pre)-Registration, Evaluation, Authorisation, Restrictions and C&L inventory, methods
2. Guidance Navigator
 - Roles and obligations
 - Based on flow charts/decision rules guiding the user to relevant detailed guidance
3. Detailed guidance
 - Steps: roles, obligations and actions
 - Methods: to be used in these steps



Challenges for industry

- 30.000 chemicals and 30.000 companies
- REACH is a Communication, Coordination and Cooperation challenge at 3 levels:
 - Intra-company (e.g. Marketing & Sales, Regulatory affairs, H&S , Product development)
 - Inter-company (other producers/importers + supply chain)
 - Multi-stakeholder level (with 25-27 MSs, Chemicals Agency; Commission, NGOs)
- REACH is a research and implementation challenge



Conclusions



1. The Commission is preparing for implementation of REACH
2. RIP's are well underway, but.....
3. Still a lot of work ahead, implementation has just started!
4. Close and (pro-)active involvement of all stakeholders is a key to success!



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
OSARs
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.

rip