



Overview of REACH Guidance

State of play & REACH Navigator tool

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Outline

- Update on the state of play of the RIPs
- How the guidance will be made available to industry
- Some key RIPs

Why REACH Implementation Projects (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

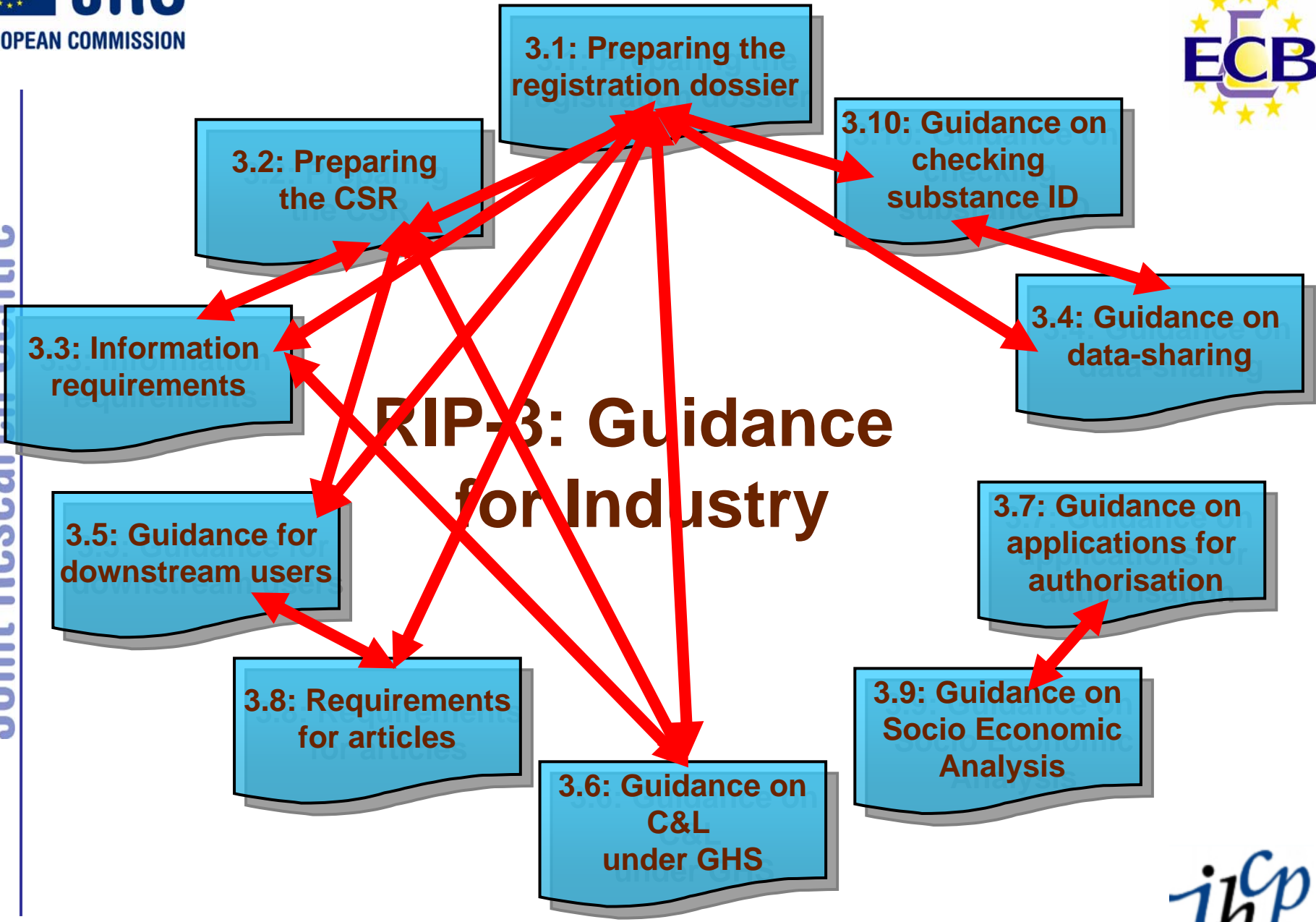
REACH Implementation Projects (RIPs):

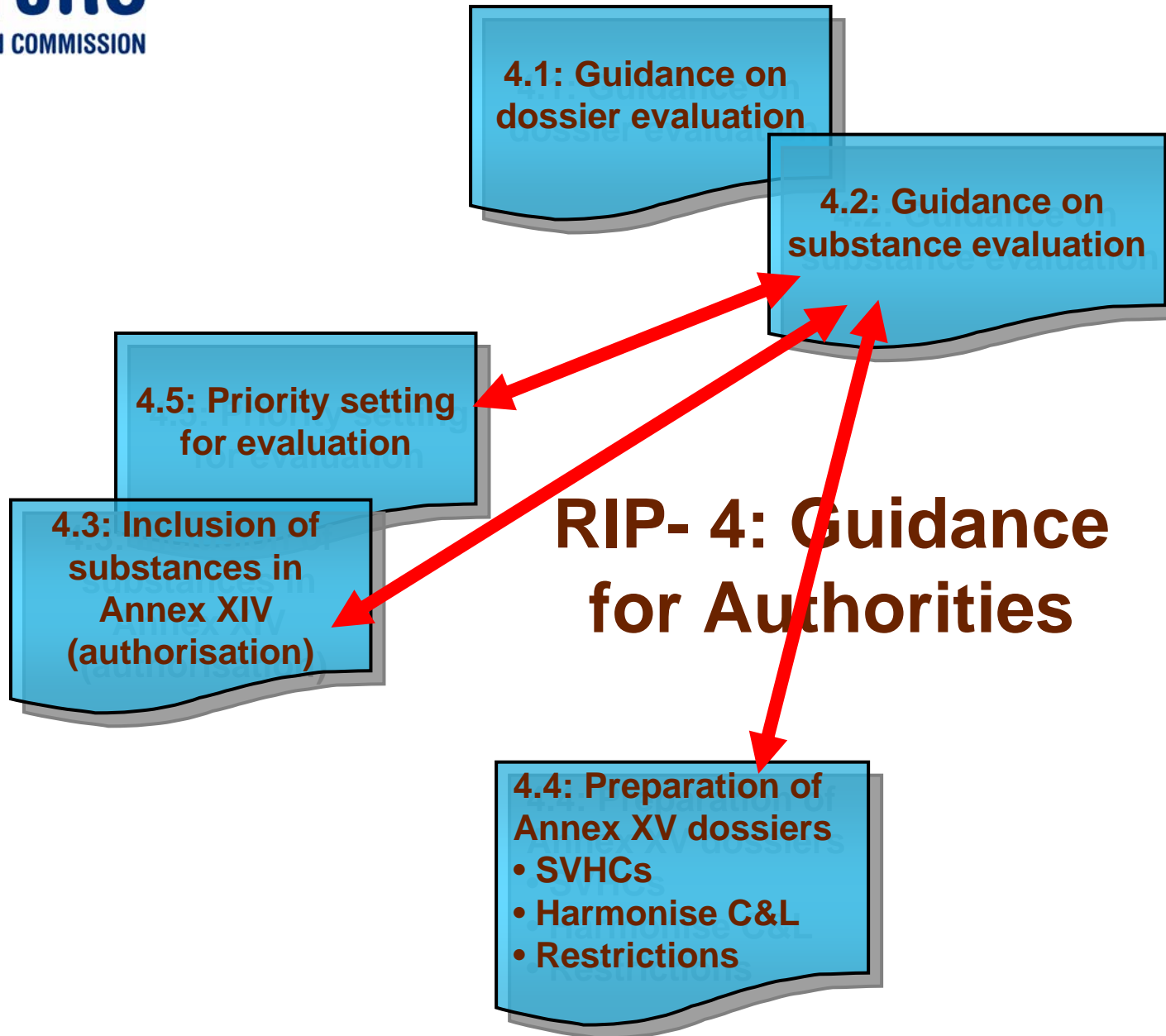
- RIP 1: Process descriptions
- RIP 2: Development of IT systems (IUCLID database and REACH-IT)
- RIP 3: Guidance Documents for industry
- RIP 4: Guidance Documents for authorities
- RIP 6: Setting up the Agency

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

Available since 12
June 2007 at:
IUCSID 5
INTERNATIONAL UNIFORM CHEMICAL INFORMATION DATABASE
<http://iucnid.eu>

RIP-3: Guidance for Industry





General management of the RIP 3/4 projects

- Overall process coordinated by the European Chemicals Bureau (ECB) of the JRC
- Most projects are tendered out via open call for tenders
- Stakeholder Expert Groups (SEG) follow closely the development process
- 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...
-by the Commission Working Group on the Practical Preparations for REACH....
-and finally handed over by the Commission to the European Chemicals Agency

Stakeholder Expert Group participation

- More than 200 experts follow the process!
- Almost all Member States involved
- 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 , Japan Business Council in Europe
- Many NGO's:
 - ETUC, FoE, WWF, ECEAE, BUAV, EEB, Greenpeace
- Others:
 - OECD, US-EPA, Health Canada, Thailand, Korea

State of play (1)

- 5 Preliminary RIP 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

State of play (2)

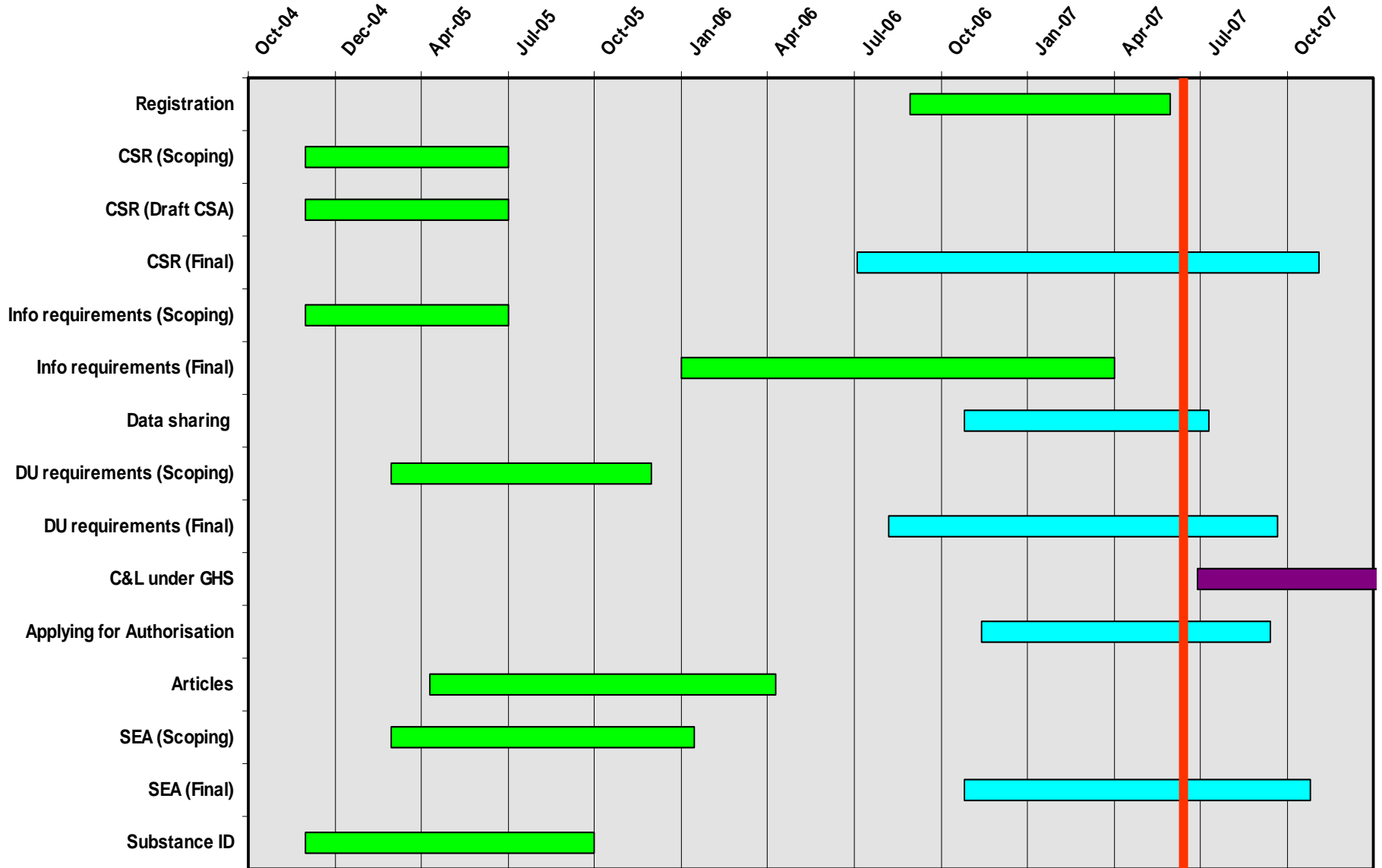
- 5 Main RIP Projects finalised:
 - RIP 3.1: Guidance on registration
 - RIP 3.8: Guidance on fulfilling the requirements for articles
 - RIP 3.10: TGD on Identification and Naming of Substances in REACH
 - RIP 4.1-4.2: Guidance on evaluation
 - RIP 4.4: TGD on the preparation of Annex XV dossiers

State of play (3)



- 7 RIP Projects running
 - RIP 3.2-2: TGD on preparing the CSR
 - RIP 3.3-2: TGD on information requirements
 - RIP 3.4: TGD on data sharing
 - RIP 3.5-2: TGD on Downstream User requirements
 - RIP 3.7: Guidance on preparing an Authorisation Application
 - RIP 3.9-2: Guidance on carrying out an SEA
 - RIP 4.3/4.5 TGD on inclusion of substances in Annex XIV and guidance on priority setting for evaluation
- One to start:
 - RIP 3.6: Guidance on Classification and Labelling under GHS

Timelines for RIP 3 projects



15 TGDs → one point of entry !

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
- Web application:
 - Concise ‘non-technical’ info on REACH’-processes
 - Serve as introduction to the more detailed guidance
 - Multi-lingual

See: <http://ec.europa.eu/echa>

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Legislation

About REACH

This section provides you with an overview of the Regulation. It lets you get started with REACH processes, chemicals covered, methods and tools used and parties involved (Actors under REACH).

[More](#)

Navigator

The Navigator is an interactive tool that lets companies answer questions on their substance and quickly find out what they need to do under REACH.

[More](#)

Guidance

REACH guidance documents provide supplementary information to the legal text. They cover all technical aspects of REACH. These documents have been produced with the assistance and endorsement of the Member States authorities, the European Commission and industry. Therefore companies should use the guidance documents as the primary source of information when they need advice on how to fulfil their REACH duties.

[More](#)

Software tools for REACH

To assist with chemical data management and registration submission under REACH, two software tools will be available: REACH-IT and IUCLID5.



NAVIGATOR

What are my obligations under REACH?

Obtain a list of your obligations by answering questions about the chemicals you handle !

[Enter the Navigator](#)



DOCUMENTS

- [Technical Guidance Documents](#)
- [REACH Legislation \(legal text\)](#)
- [Formats](#)
- [Other Documents](#)



What can you find on this website?

This website assists industry and authorities to understand their obligations under REACH and provides guidance on how to fulfil them. It contains 5 main elements:

- **About REACH**
gives an overview of the processes foreseen by REACH, its scope and the main obligations of the actors involved in REACH
- **Navigator**
is an IT-tool to help industry determine its obligations under REACH
- **Guidance documents**
provides the Guidance Documents on REACH processes and methods, to be used by industry and authorities.
- **Formats**
contains the key templates that industry and authorities can use in the context of REACH (e.g. format for Chemical Safety Report, format for Substance Evaluation Report, formats for Annex XV dossiers)
- **Legislation**
contains different legislative texts related to EU chemicals policy, in particular the **REACH Regulation** in all official languages of the EU

Some parts of this website are still under construction, especially "Guidance Documents", and will be regularly updated with new documents as soon as they become available.

Parts of this website are accessible in all languages of the European Community. For the parts which are not translated, the default language used is English.

If you need an overview of REACH, we recommend that you start with "about REACH".

Basics of REACH

- Pre-registration
- Data-sharing
- Registration
- Evaluation
- Authorisation
- Restrictions
- Classification & Labelling
- Communication in the supply chain
- Enforcement

REACH Processes

Pre-registration

[Manufacturers and importers](#) must pre-register substances that are already on the EU market, if they want to benefit from transitional arrangements that allow registering them at a later stage. Pre-registration also enables registrants to share data with other registrants and avoid carrying out redundant tests. The pre-registration period is limited from 1 June 2008 to 1 December 2008.

Registration

REACH requires manufacturers and importers of chemical substances (≥ 1 tonne/year) to obtain information on the physicochemical, health and environmental properties of their substances and use it to determine how these substances can be used safely.

Each manufacturer and importer must submit a registration dossier documenting the data and assessments to the [Agency](#).

Evaluation

The Agency will perform dossier evaluation to assess testing proposals made by the registrant or to check that the registration dossiers comply with the requirements. The Agency will also co-ordinate substance evaluation, which will be conducted by the Member States to investigate chemicals of concern.

Authorisation

Authorisation may be required for some substances of very high concern that are prioritised and included in Annex XIV .

Companies applying for authorisation will have to demonstrate that risks associated with uses of these substances are adequately controlled or that the socio-economic benefits from their use outweigh the

See also:

- > Glossary: [PBT](#)
- > Glossary: [vPvB](#)
- > Glossary: [SVHC](#)

NAVIGATOR

- Interactive tool on the Agency website
- Sequence of questions (supported by guidance) to be answered by the user
- The outcome → list of obligations for the user
- Each of the obligations will be linked to guidance (RIP projects) describing how to fulfil the users' obligations
- Translation of the Navigator foreseen

Questions

History

Restart Navigator

▼ My comments



Question n°1

Is your substance any of the following?

- A radio-active substance
- A substance under customs supervision
- A substance used exclusively in the interest of defence, covered by national exemption
- A waste
- A substance used exclusively as a non isolated intermediate
- A "transported substances" (i.e. you exclusively transport the concerned substance)

- No
 Yes

OK, next question >

Help

In order to answer this question guidance is given below on:

- [Radio-active substance](#)
- [Substance under customs supervision](#)
- [Substance used exclusively in the interest of defence](#), covered by national exemption
- [Waste](#)
- [Substance used exclusively as a non isolated intermediate](#)
- [Transported substances](#)

Radio-active substances

Radio-active substances are substances that contain one or more radionuclides of which the activity or concentration cannot be disregarded as far as radiation protection is concerned. In other words, they are substances which give off such a degree of radiation that there is a need to protect people and the environment against that radiation.

Radio-active substances were already exempted from notification under Directive 67/548/EEC on classification, packaging and labelling of dangerous substances, and the REACH Regulation exempts them from its application altogether. The reason for this exemption is that

Timing

- Overall guidance package and website were ready at Entry into Force (1st June 2007)
 - About REACH
 - Navigator
 - RIP 3.1: Registration guidance (including guidance for intermediates, Monomers and Polymers, and PPORD)
 - RIP 3.10: Guidance on identification and naming of substances under REACH
- Other RIPs will gradually be inserted in the months after

Some key RIPs

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
- Two-level guidance: Concise and reference TGDs
- (further) Development of the exposure scenario (ES) concept:
 - framework and examples
 - RMM library
 - ESs for preparations
 - How to incorporate ESs into SDSs ?
- Inclusion of new RA methodology (e.g. DNEL concept)
- Options for software development

→ Scoping report available: Final guidance under preparation

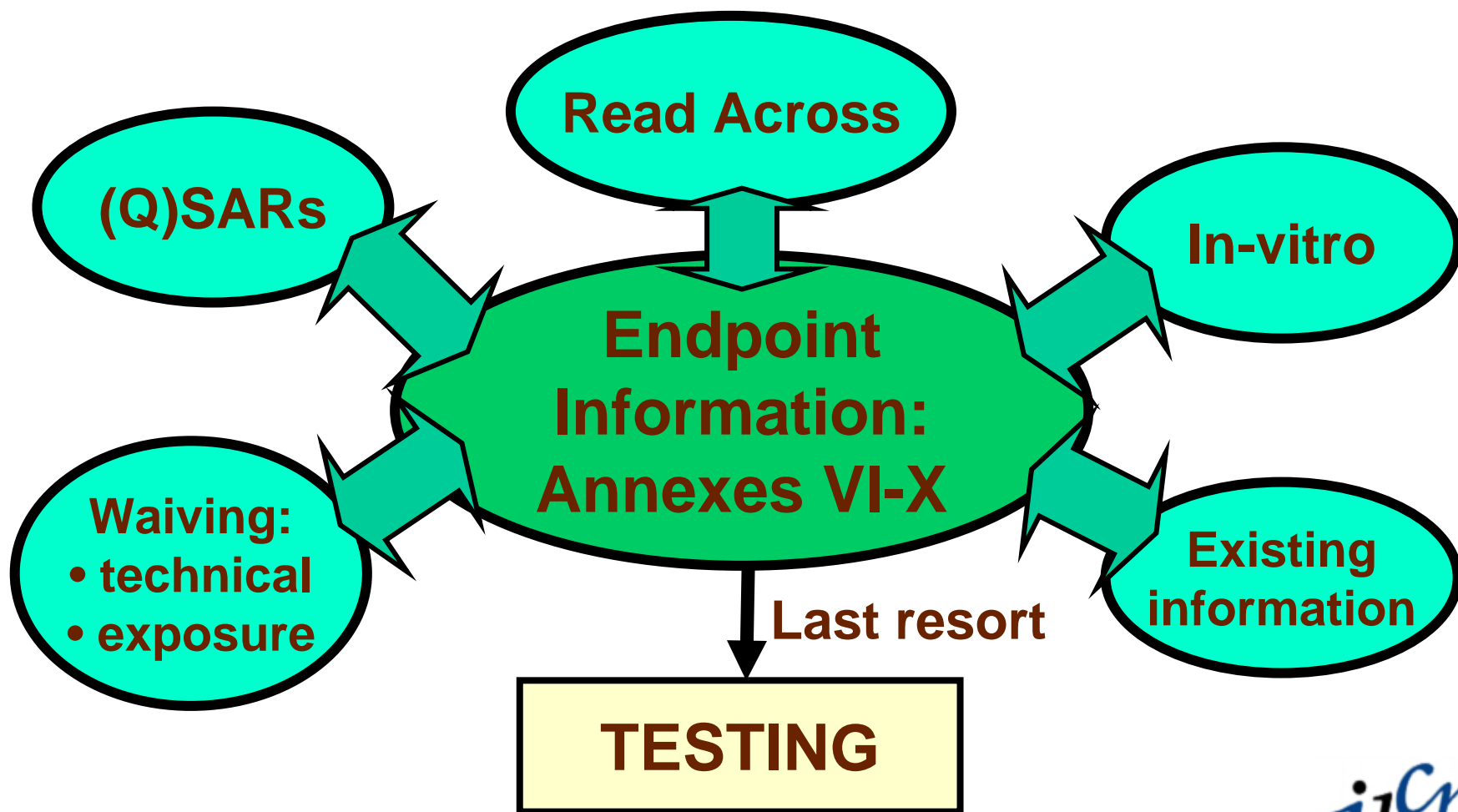
TGD on Information requirements under REACH (RIP 3.3)



- Guidance for Industry on:
 - how to fulfill the information requirements on intrinsic properties (REACH Annexes VI to XI, adapted as of Annexes VI and XI) and
 - how to use all information and testing in an optimal way for decision-making under REACH
- Providing for:
 - Carrying out Chemical Safety Assessment (CSA)
 - including whether substance is PBT or vPvB
 - Classification and labelling (C&L)
 - including assessment whether a substance is CMR

Integrated Testing Strategies

Joint Research Centre



Guidance explains and illustrates:

- How to find, assess and use existing information
- How to implement the rules for adaptation as provided in the different annexes
- How and when to use alternative information and approaches such as:
 - In vitro methods
 - (Q)SARs
 - Grouping and read-across
 - Toxicokinetics
- How and when the information requirements may be adapted (including waiving) according to the provisions of Annex XI including:
 - Exposure considerations
 - Scientific and technical considerations

→ Draft guidance is available !

Guidance for Downstream Users (RIP 3.5)

Objective:

- Develop easy to use guidance
- Target all types of DU (and distributors)
 - SME
 - Inexperienced user
- Motivate DU to take pro-active action
- Available:
 - Draft final guidance on role identification and obligations
 - Draft final guidance on preparing for REACH
 - Draft guidance on preparations and DU CSR is tested in case studies over the summer
- Final report available by mid October 2007

Guidance on requirements for substances in articles (RIP 3.8)



Objective:

- Guidance for producers/importers of articles on whether or not they have obligations according to REACH Article 7 and 33
 - Registration ?
 - Notification ?
 - Communication related to SVHC content ?
- Draft guidance available but based on Council Compromise text
- Discussion ongoing to clarify two issues:
 - Whether the 0.1 % SVHC content shall refer to an article as produced/imported or to each homogeneous part
 - Whether the borderline cases discussed in the guidance as falling under article 7(1) should actually rather fall under Article 6
- The Final guidance should be ready end of 2007

Wait for guidance or act now?

Act now !



- What is your portfolio? Use RIP 3.10
- What type of actor are you? Use the Navigator!
- What data do you have, what information do you need? Use RIP 3.3
- Check available information sources
- What RMMs do you or your customers use? The development of Exposure Scenarios requires dialogue and cooperation within the supply chain..... RIP 3.2-1 workflows and initial guidance are available
- Talk to your internal/external colleagues, business associations, industry helpdesks
- Contact your national helpdesk or ECHA
- Follow the news on the guidance website!!!

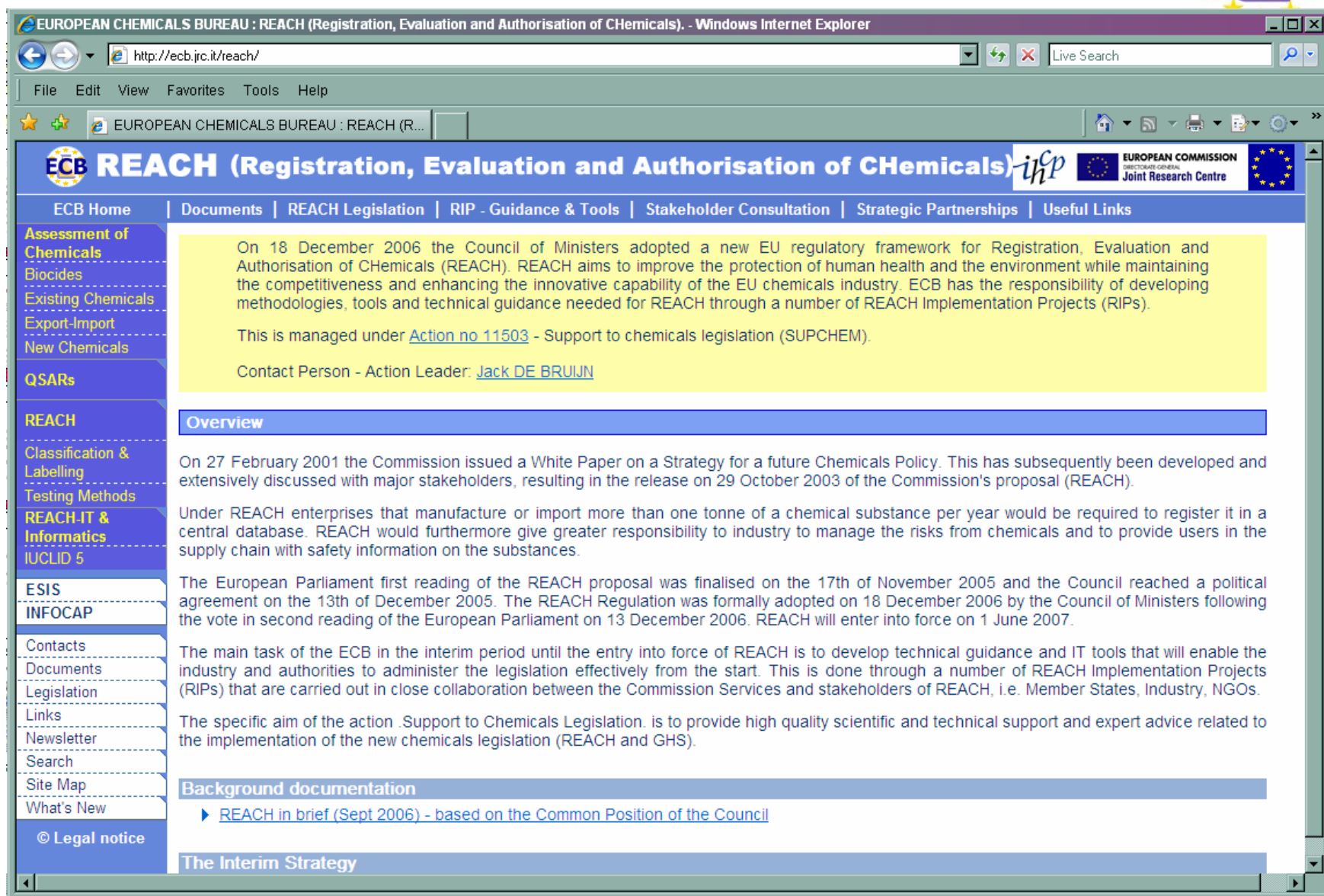


Conclusions

1. The Commission, together with stakeholders, is preparing for implementation of REACH
2. RIPs are well underway
3. You can wait for the guidance but you better act now!

Further information on RIPs

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



EUROPEAN CHEMICALS BUREAU : REACH (Registration, Evaluation and Authorisation of Chemicals) - Windows Internet Explorer

http://ecb.jrc.it/reach/

File Edit View Favorites Tools Help

EUROPEAN CHEMICALS BUREAU : REACH (R...

ECB REACH (Registration, Evaluation and Authorisation of Chemicals)

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ECB Home | Documents | REACH Legislation | RIP - Guidance & Tools | Stakeholder Consultation | Strategic Partnerships | Useful Links

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QSARs

REACH
Classification & Labelling
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On 18 December 2006 the Council of Ministers adopted a new EU regulatory framework for Registration, Evaluation and Authorisation of Chemicals (REACH). 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 11503](#) - Support to chemicals legislation (SUPCHEM).

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 29 October 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 European Parliament first reading of the REACH proposal was finalised on the 17th of November 2005 and the Council reached a political agreement on the 13th of December 2005. The REACH Regulation was formally adopted on 18 December 2006 by the Council of Ministers following the vote in second reading of the European Parliament on 13 December 2006. REACH will enter into force on 1 June 2007.

The main task of the ECB in the interim period until the entry into force of REACH is to develop technical guidance and IT tools that will enable the industry and authorities to administer the legislation effectively from the start. This is done through a number of REACH Implementation Projects (RIPs) that are carried out in close collaboration between the Commission Services and stakeholders of REACH, i.e. Member States, Industry, NGOs.

The specific aim of the action .Support to Chemicals Legislation. is to provide high quality scientific and technical support and expert advice related to the implementation of the new chemicals legislation (REACH and GHS).

Background documentation

▶ [REACH in brief \(Sept 2006\) - based on the Common Position of the Council](#)

The Interim Strategy