European Commission

Preparing for REACH
the new EU chemicals regulation

Standard Presentation for Industry Audiences

Brussels - January 2007

European Commission, DG ENTR, REACH Unit

This presentation does not necessarily reflect the official opinion of the Commission

Outline

- REACH regulation: history & basic set-up
- An overview of the basic steps
- An overview of the changes vis-à-vis the Common Position
- An overview of the REACH Implementation Projects (RIPs)
- Draft Technical Guidance Documents and Overall Guidance: Work in Progress
- Commission tasks after entry into force
- The European Chemicals Agency ECHA
- Helpdesks under REACH
- Preparing for REACH: recommended first actions for industry

The adoption of REACH: a short history

- Feb 2001 — White Paper on "Strategy for a future Chemicals Policy"
- May 2003 — Internet consultation: 6000+ comments received
- Oct 2003 — Commission adopts REACH proposal
- Dec 2006 — Council and Parliament adopt amended REACH proposal in Second Reading of co-decision procedure

- 30. 12. 2006 — REACH published in the Official Journal
- 01. 06. 2007 — REACH enters into force
- 01. 06. 2008 — Official entry into operation of the Agency
  Pre-registration of phase-in substances starts
  Registration of non-phase-in substances starts

REACH

- **One single and coherent system**
  for new and existing chemicals
- **Core elements:**
  - Registration of substances ≥ 1 tonne/yr (staggered deadlines)
  - Information in the supply chain
  - Evaluation of some substances by Member States
  - Authorisation only for substances of very high concern
  - Restrictions - the safety net
  - Agency to manage system
- **Focus on priorities:**
  - high volumes (as a proxy for potential risk)
  - greatest concern (substances & uses with highest risk)
- **Shift of responsibilities**
  from public authorities towards industry

Scope of the regulation

⇨ *REACH applies to the manufacturing, import, placing on the market and use of substances*

- However, there are **exemptions** for certain:
  - Substances
  - Uses of substances
- **Reduced obligations** for R&D (research, product and process related research and development (PPORD)), polymers and intermediates
- Note that substance definition includes metals, as has been the case in the EU for the last decades

Manufacturers/Importers: Registration

- **Pre-registration:** closing date is 1 December 2008
- **Registration** for substances ≥ 1 tonne per year
- **Imports**: *registration by EU-importer or the "only representative" of the non-EU company*
- **Chemical Safety Report** (CSR) for all substances ≥ 10 t per year

⇨ *In the absence of available information,*
tests may have to be conducted

- ⇨ *Data sharing (in particular for vertebrate tests)*
- ⇨ *Substance Information Exchange Fora (SIEFs)*

Manufacturers/Importers: Registration

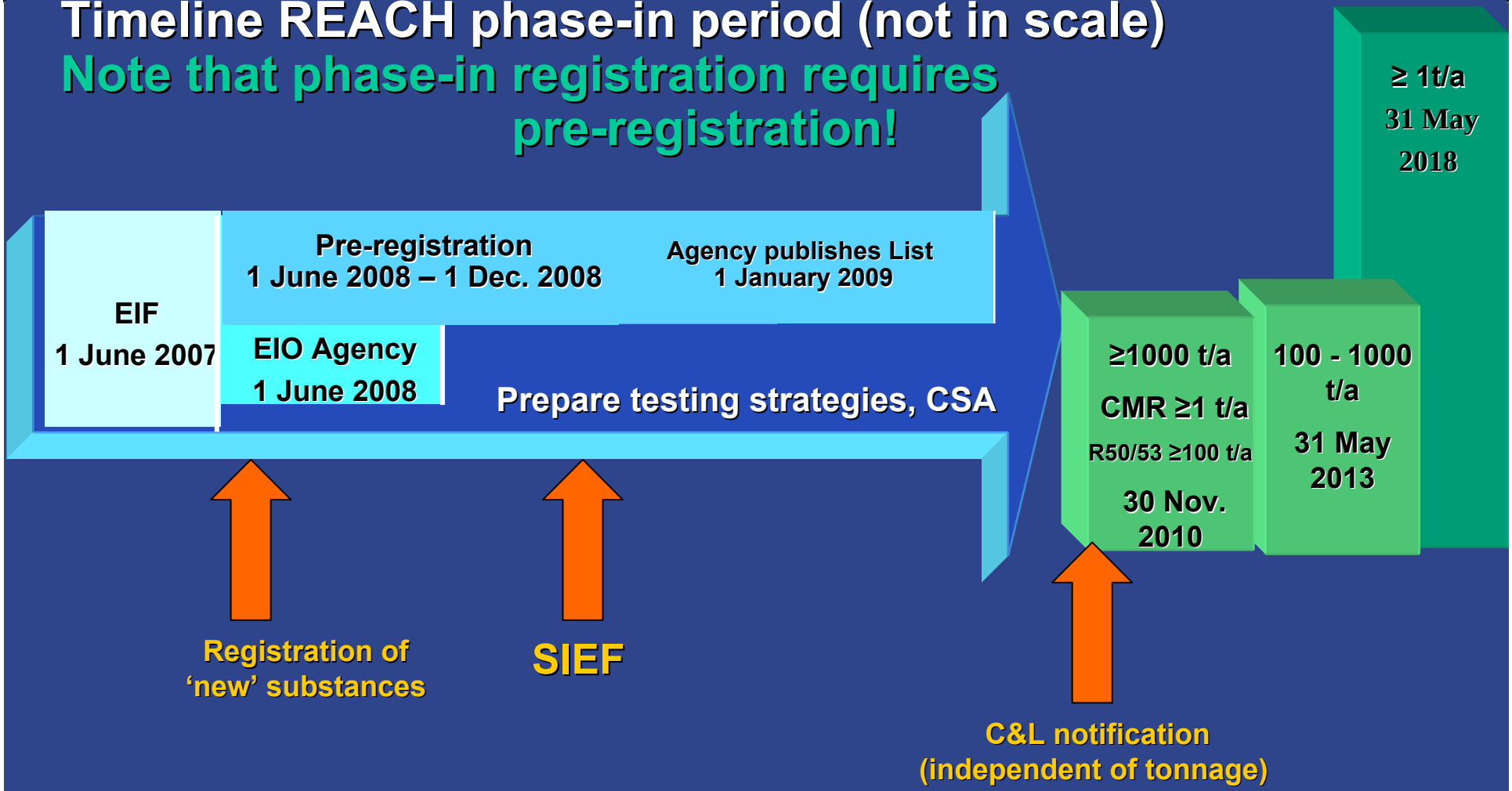
- **Timetable:**
  - **Non phase-in substances:**
    - A 67/548/EEC notification automatically becomes a registration
    - When not already notified by the company:
      registration required before production or import can take place
  - **Phase-in substances:**

    benefit from transition periods ***if pre-registered***
    - Pre-registration: 1 June 2008 – 30 November 2008
      (except where newly manufactured / imported)
      - Identify substance, manufacturer, tonnage band/deadline
      - Agency will publish list
    - Registration: Transition period depending on the tonnage band

Tasks and timelines

Timeline REACH phase-in period (not in scale)

Note that phase-in registration requires pre-registration!



Downstream Users Obligations

- ***Downstream Users** are users of chemical substances that are neither manufactured nor imported by the company itself*
- ***Be careful !** In case input chemical is directly imported from outside the EU: REACH considers you as an importer and not as Downstream User!*

- **Key question: Do you receive Safety Data Sheets?**
  - **If not:**
    - **only limited obligations under REACH**
  - **If yes & you've made your use known to supplier**
    - **apply the relevant risk management measures identified in the SDS**
  - **If yes & you've chosen to do your own Chemical Safety Report**
    - **apply the management measures identified in your own assessment**

Downstream Users Rights

- To make their uses known to manufacturers/importers,

  However, to get suppliers' exposure scenario & support they need to provide the relevant data

- To carry out their own CSA

  (e.g. for confidentiality reasons)

- To contribute to SIEFs

Substances in Articles (Article 7)

- > 1 tonne / year per Manufacturer / Importer
- Not registered for that use

- Intended to be released (regardless of hazard)

General obligation to **register**

- Timeline in accordance with (phase-in) deadlines

- Substance of Very High Concern (CMRs, PBTs and vPvBs, etc.)
- Placed on candidate list for authorisation
- Concentration of > 0.1 % weight-by-weight

Obligation to **notify** the Agency

- except where there is no exposure
- At the earliest 1 June 2011, *and* 6 months after SVHC placed on candidate list

Agency may require registration

Evaluation

- **Dossier evaluation**:

  Checking compliance of registration dossiers

  Checking of test proposals

- **Substance evaluation**:

  Checking whether there is a need

  for further information on a substance

Authorisation/Restriction

- **Authorisation**:

  for Substances of Very High Concern

  - Identification of SVHC
  - "Sunset date" after which manufacturing and use is only allowed when covered by an authorisation

- **Restriction**: only minor changes

  compared to existing system (Directive 76/769/EEC)

  - In addition to "marketing & use", now also manufacturing covered
  - Title VIII and Annex XVII apply from 1 June 2009
  - Until 1 June 2013, Member States allowed to maintain own existing and more stringent restrictions under Annex XVII

Changes vis-à-vis the Common Position (1)

- **Definitions:**

  "per year" is taken to mean "three-year average"

  terms "exposure scenario", "use & exposure category" clarified

- **First registration deadline after 3 ½ years (1 Dec 2010)**
  which also shifts deadlines for:
  - Agency reaction to test proposal
  - Notification to the Classification & Labelling inventory
  - First Community Rolling Action Plan for substance evaluation
  - Notification of Substances of Very High Concern in articles
- **PPORD exemption on registration**

  Also non-marketed substances may get extra 10 year extension

Changes vis-à-vis the Common Position (2)

- **Extra incentives to prevent unnecessary animal testing:**
  - Agency will publish test proposals and invite third parties to submit data that would avoid vertebrate testing
  - Explicit allowance for future alternatives to *in vivo* tests
  - Regular reports from Agency and Commission on non-animal methods
- **Information exchange further encouraged while safeguarding Confidential Business Information**
  - Early registrants take part in the SIEF
  - Downstream Users may ask Agency to publish substance ID when it is not pre-registered, helping to assure continued supply
  - Pay for studies up to 12 years
  - Use as intermediate is normally Confidential Business Information
  - Protection of IUPAC name may be claimed for substances:
    - When non-phase-in
    - When only used as intermediate, or for R&D and PPORD uses

Changes vis-à-vis the Common Position (3)

Authorisation Title puts stronger emphasis on substitution:

- If the mandatory "Analysis of alternatives" finds suitable alternatives, the application must also include a substitution plan with timetable
- When no such alternatives are found, the application must provide information on any relevant R&D activities, if appropriate
- During a review, the Commission may require a substitution plan when it decides that there are suitable alternatives available
- PBT substances cannot invoke the "adequate control route"
- By 1 June 2013, the Commission to consider whether to exclude Endocrine Disruptive Substances from the scope of the "adequate control route"

Changes vis-à-vis the Common Position (4)

Further changes include:

- **Heavier procedure** required (i.e. "regulatory procedure with scrutiny") for:
  - Restrictions on the use of substance, and
  - Amending Annexes to the legal text
- **Right on information on Substances of Very High Concern** present in articles (in concentrations above 0,1 % $^{w}/_{w}$):
  - Consumers now have this right on information as well
- **Enhanced role European Parliament in supervising Agency**
- **Agency will come with guidance** on
  - Substances in Articles, and
  - Risk Communication

Implementing Legislation & Review Tasks of the Commission

- **Commission Regulations** needed on:
  - Fees
  - Board of Appeal arrangements
  - Test methods

} *same list as under Common Position*

- ***Imminent* Review Tasks** for the Commission include:
  - By 1 June 2008 — Review Annex I: on CSA & CSR (Chemical Safety Assessment & Report) Annexes IV & V (substances exempted from registration)
  - By 1 Dec 2008 — Review of the PBT criteria of Annex XIII Annex XI, section 3 (criteria exposure-based waiving of tests)
  - By 1 June 2010 — Amend Annex XVII (restrictions) in the light of ongoing work

Implementing goals of the Commission

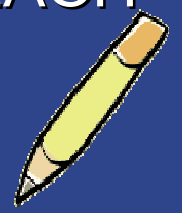
- **Intensify the preparation to implement REACH smoothly:**
  - **Drafting the Technical Guidance Documents,**
  - **Preparing the necessary software tools (IUCLID 5 and REACH IT),**
  - **Setting up ECHA: the Chemicals Agency in Helsinki**

➔ Important:

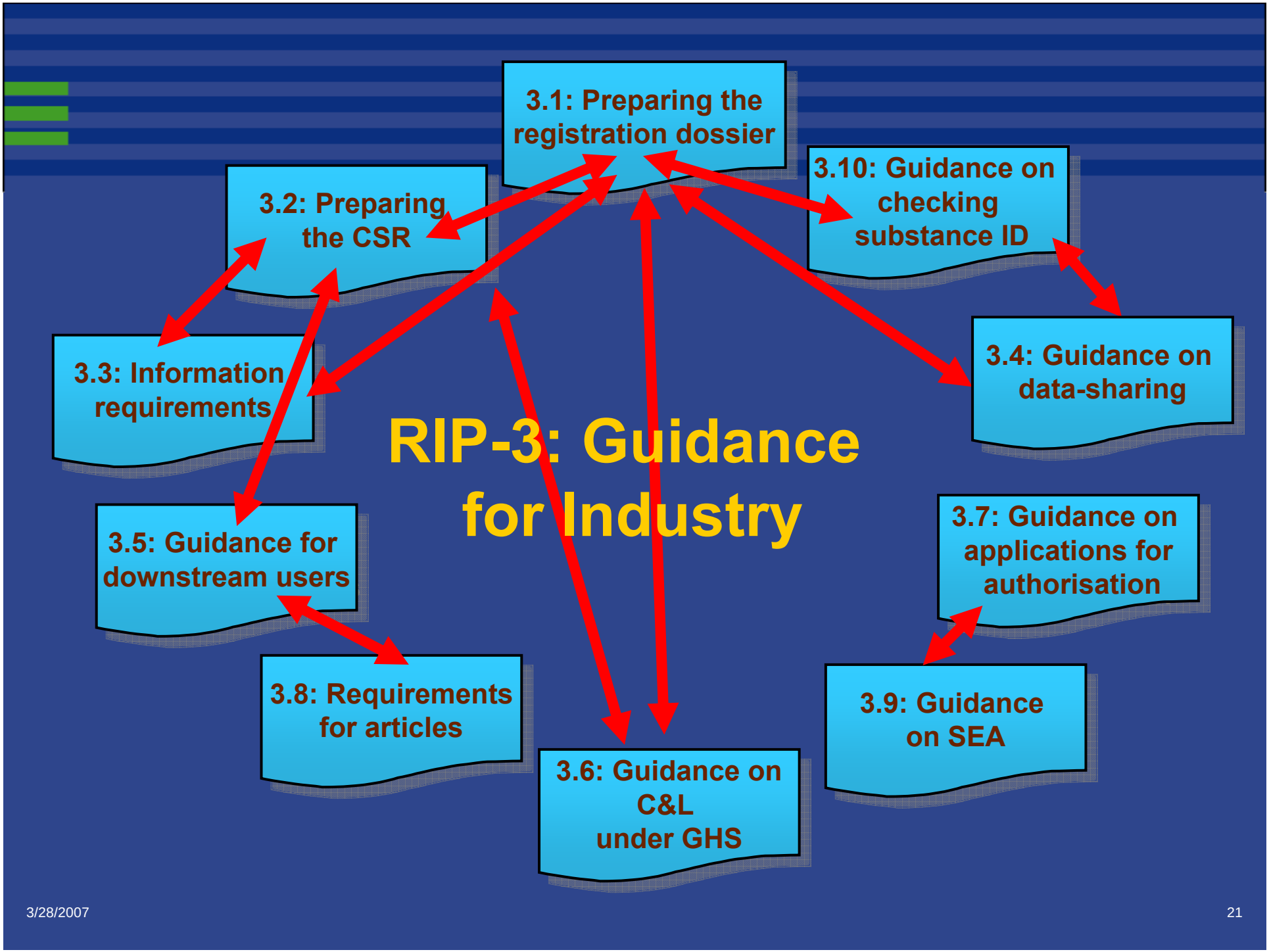
- to provide key elements of the guidance by entry into force
- to make REACH workable for SMEs
- to get the Agency operational on time

REACH Implementation Projects - RIPs

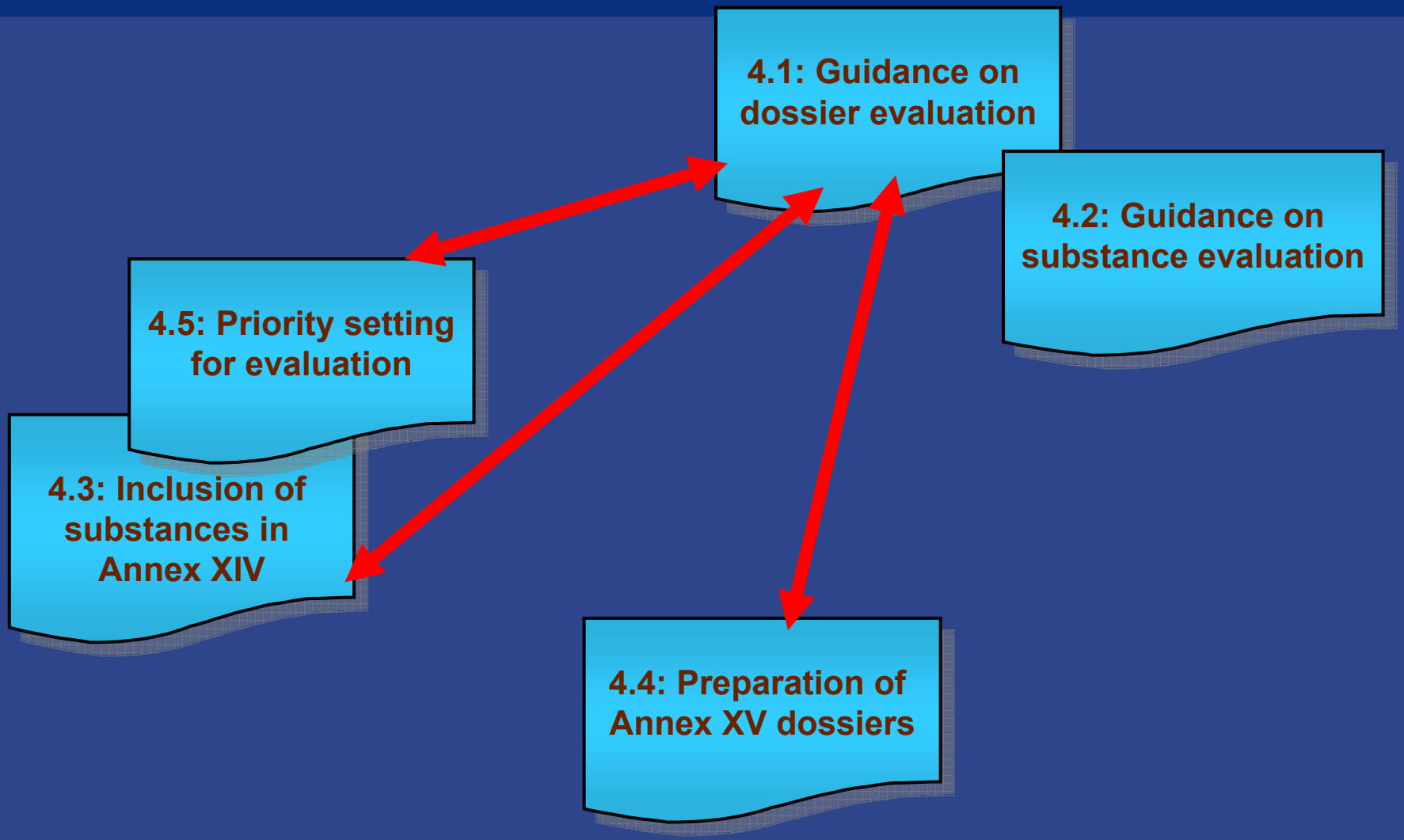
AIM: To develop in close collaboration with all stakeholders guidance helping to fulfil the obligations under REACH



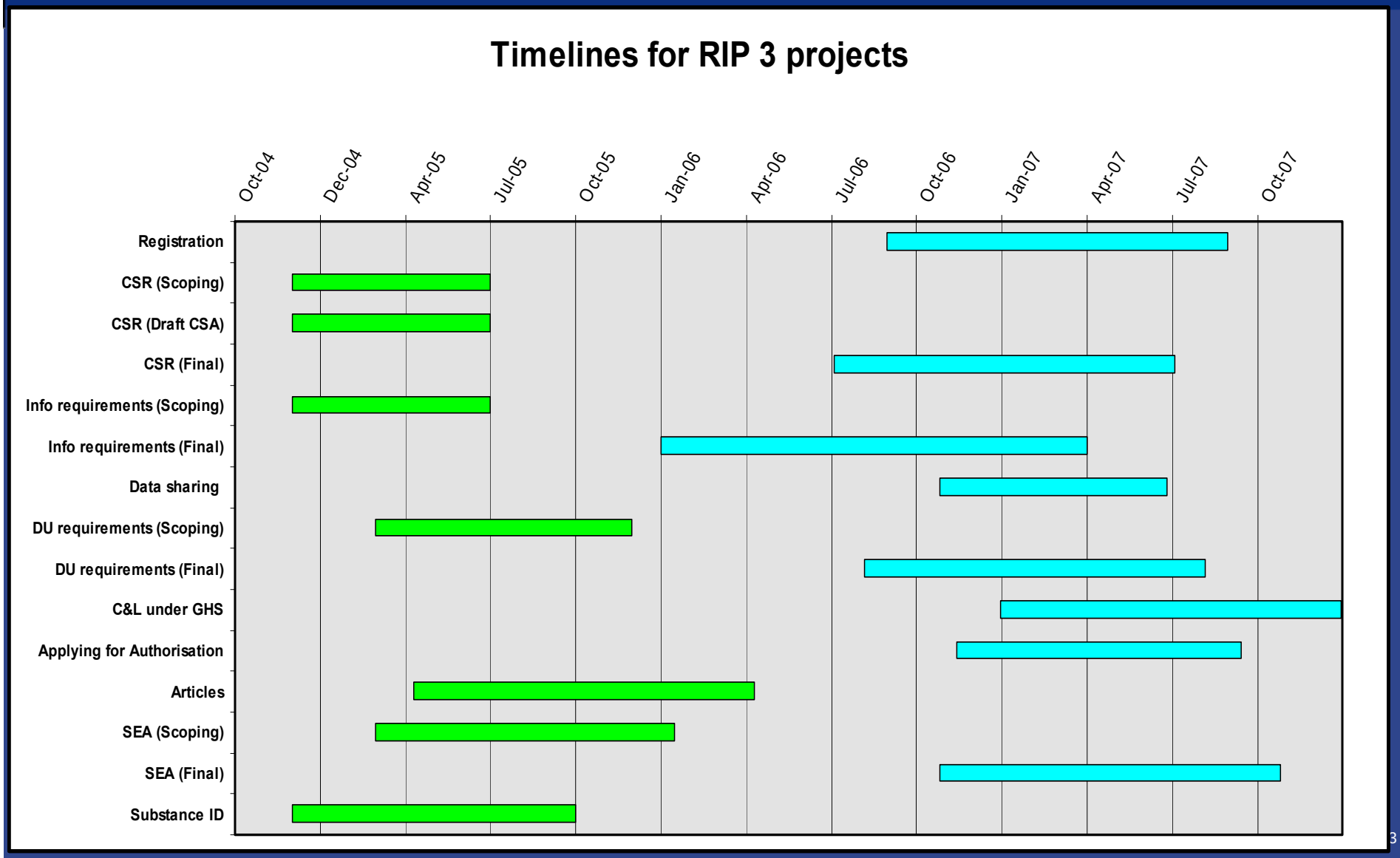
- **RIP 1:** REACH Process Description; ✓
- **RIP 2:** REACH – IT;
- **RIP 3:** Technical Guidance and Tools for Industry;
- **RIP 4:** Technical Guidance and Tools for Authorities;
- **RIP 5 & 6:** Setting up the Agency
- **RIP 7:** Preparation of the new tasks for the Commission
- **RIP 8:** Agency Standard operational procedures


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: Guidance for Industry
3.5: Guidance for downstream users
3.7: Guidance on applications for authorisation
3.8: Requirements for articles
3.9: Guidance on SEA
3.6: Guidance on C&L under GHS

RIP- 4: Guidance for Authorities



Timelines for RIP 3 projects



The overall guidance package

- **Objective**:
  - Should allow stakeholders to **quickly understand REACH** and their roles and obligations under REACH
  - Should be **as exhaustive as possible** to cover the users´ needs

- **Web application**;

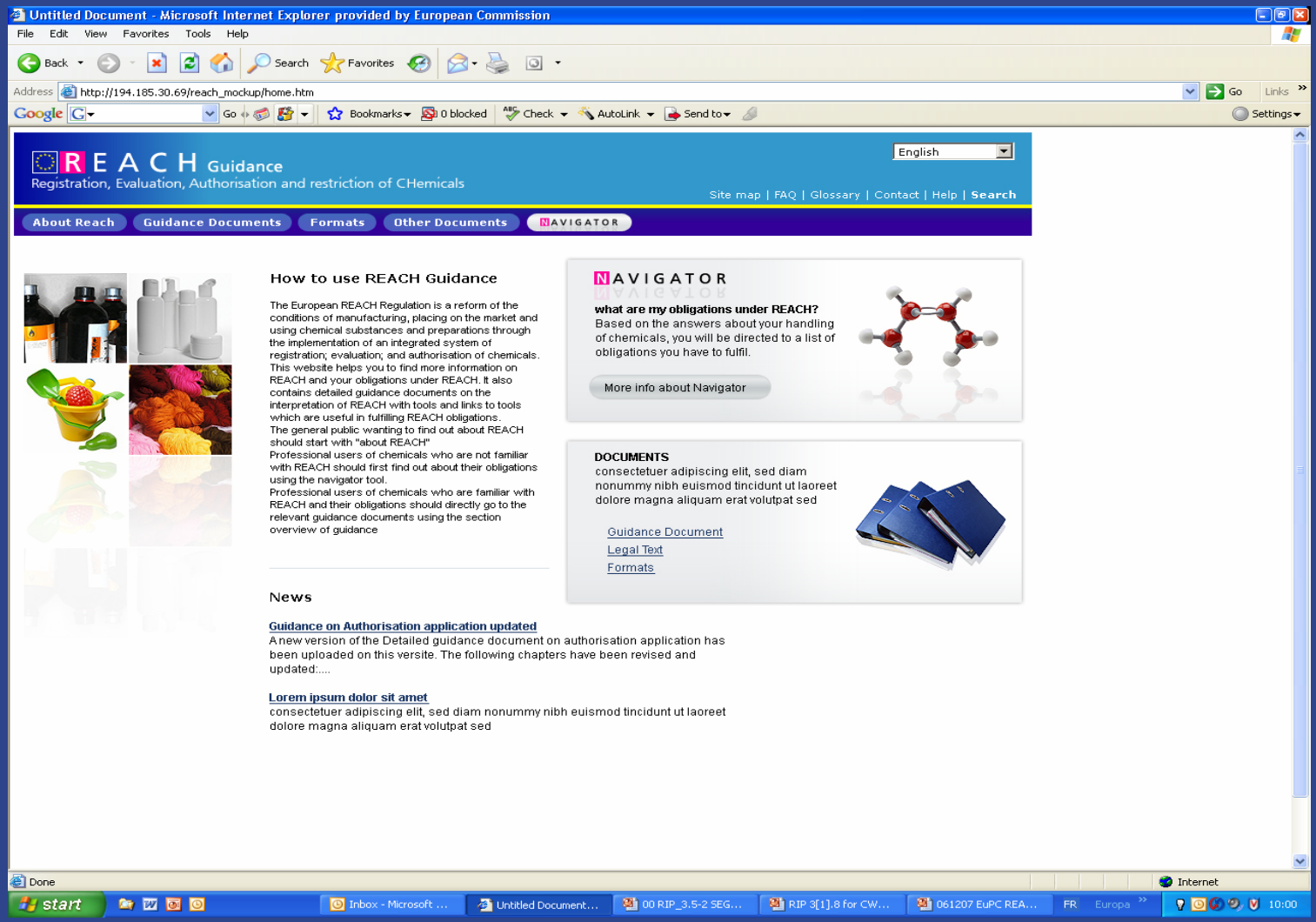
  planned to be available at entry into force, 1 June 2007

Main elements guidance package

- "About REACH"
  - Short explanation of REACH for inexperienced users
- Guidance Navigator
  - Based on a series of questions, the user will receive:
    - a list and short description of his obligations
    - references/links to the relevant parts of legislation and guidance
- Technical guidance documents
  - Containing all relevant information (based on the results from RIP 3 but not necessarily identical)

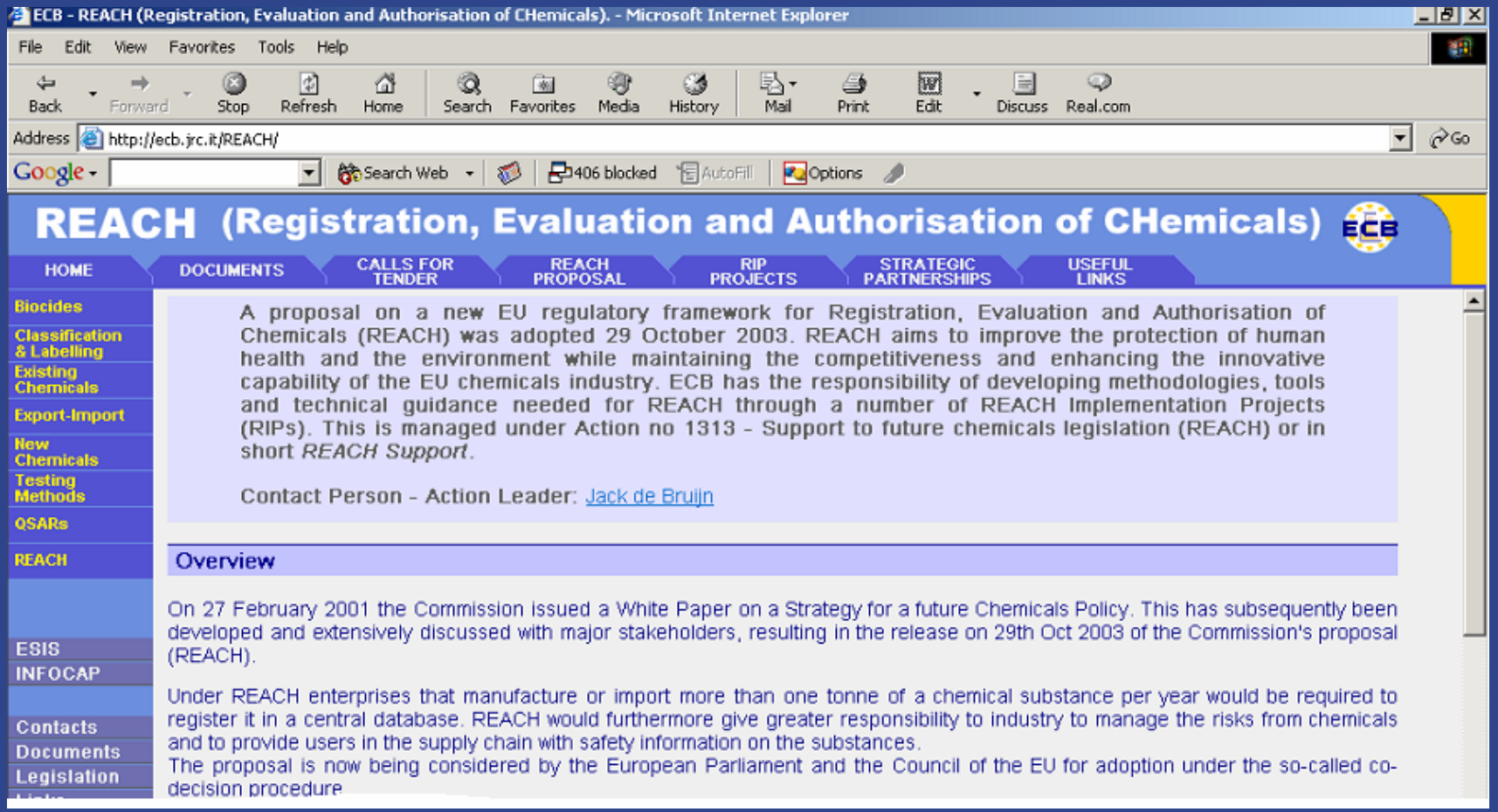
⇨ *in addition: formats, search functions, glossary, link to Frequently Asked Questions, helpdesk etc.*

What might the guidance look like?



Further information on RIPs

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



Commission tasks after entry into force

- **"Comitology Decisions"**

  Apply to:

  1. Implementing measures, e.g. → Testing methods; Fees regulation

  2. Amendments -> Annexes
     e.g. review Annexes I, IV and V by 1 June 2008
  3. Restrictions and Authorisation decisions;
     On substance evaluation (if no unanimous agreement in MS committee)

  In some cases, the new Regulatory Committee has to apply the scrutiny procedure (i.e. on top of Council, EP has also blocking power)

- **Specific roles in implementation**
  as defined in the Regulation

European Chemicals Agency
ECHA

- ECHA is the Europe's central Agency for the chemicals regulation
  - One of the few agencies that can take legally binding decisions
- In June 2007, Agency will start up in Helsinki:
  - First staff moving in
  - Making available Guidance and providing Helpdesk function
- From 1 June 2008 the Agency will have the following main tasks :
  - Technical Guidance Documents and provision of assistance to registrants of substances,
  - Deals with registration applications
  - Execution of completeness check and dossier evaluation,
  - Co-ordination of substance evaluation
  - Tasks with authorisation and restrictions

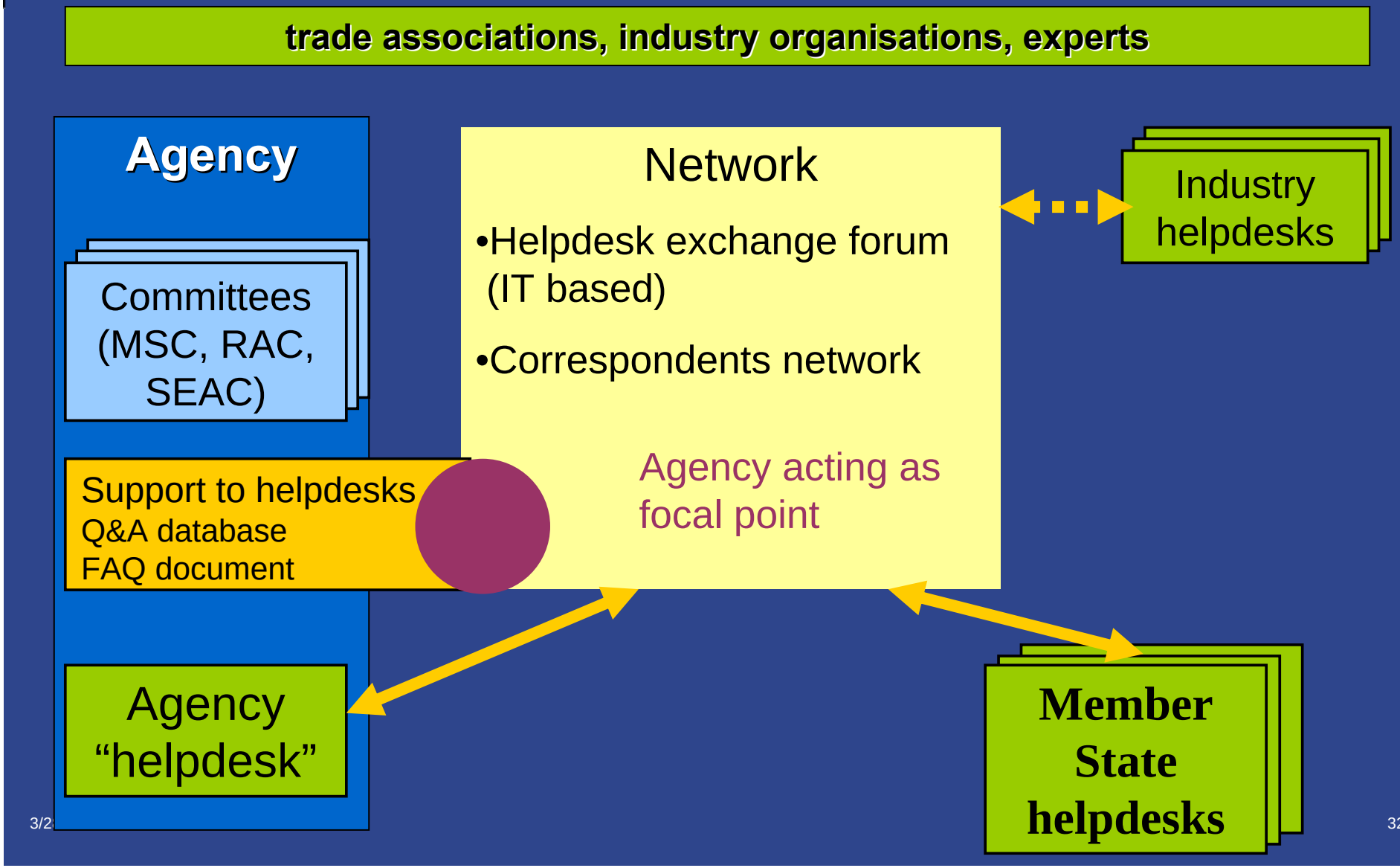
Helpdesks under REACH

- **Member States helpdesks**
  - Individual advice on obligations under REACH
- **Agency helpdesk for registration,**
  including helpdesk on IUCLID5
  - General advice on registering according to Article 77 (2) h (the helpdesk of the helpdesks)
  - Information on dossiers
- **Agency support for national helpdesks**
  - Coordination of network of helpdesks

The planned network of Member States helpdesks

- **IT based exchange forum** to discuss non-standard questions before they are answered by the national helpdesk
  - Questions and answers saved in internal Q&A database
- **Correspondents network** to discuss organisational questions relating to the network and to resolve inconsistencies in answering questions
- **FAQ document** with standardised questions and agreed answers will be published on the Agency website
- **Industry helpdesks will be partners with a complementary function** (e.g. hands-on advice) and representatives will be invited as observers to the correspondents network

Network of helpdesks



Enforcement of REACH

- REACH Enforcement is competence of Member States;
  the Agency hosts the FORUM.

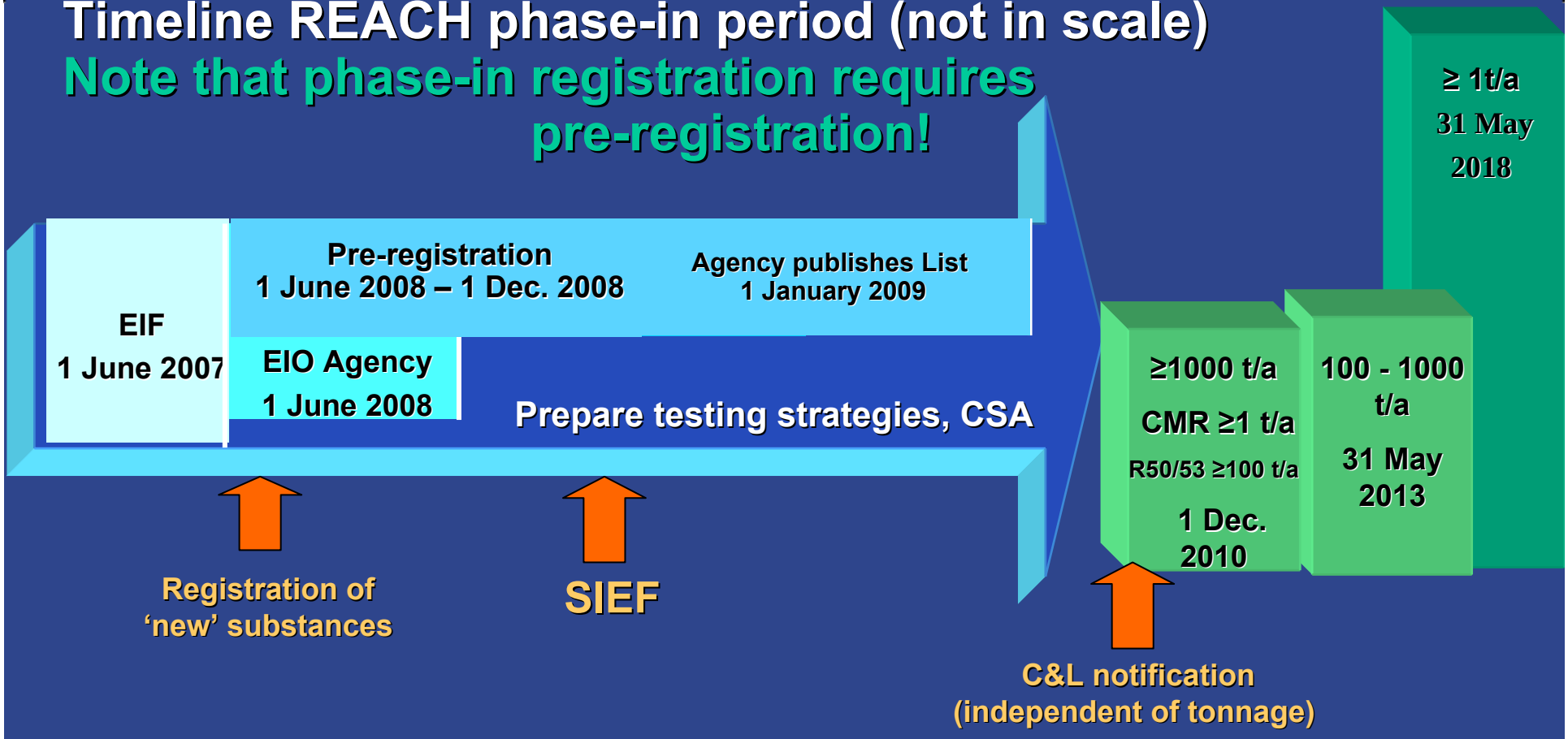
- FORUM for Exchange of Information on Enforcement
  shall coordinate a network of Member States authorities responsible for enforcement
  establishment of the Forum will follow the clear instructions provided by the legal text (Art. 77(4) & Art. 86)

  Its Tasks include:
  - Identifying enforcement strategies and best practices
  - Coordinating exchange of inspectors and joint inspections
  - Developing working methods and tools of use to local inspectors
  - Developing an electronic information exchange procedure
  - Liaising with industry, with particular regard to SME-specific needs

Tasks and timelines (repeat)

Timeline REACH phase-in period (not in scale)

Note that phase-in registration requires pre-registration!



What should companies do NOW?

EU manufacturers / importers: What should they do now?

On the main regulatory steps of immediate relevance:

Pre-registration (to gain right on phase-in registration periods)

1) Collect available information
2) Locate other relevant information holders & consider consortium
3) Share Data

Registration (normally together with the other substance suppliers)

1) Carry out the Chemical Safety Assessment & write the Chemical Safety Report
2) Compile and submit Registration Dossier
3) Communicate down the supply chain

{ Only for substances supplied ≥ 10 tonne

Do not forget to pre-register in time!

Start information collection and communication!

Points of immediate relevance for non-EU companies

- **Pre-registration** required for extended registration:

  Your EU-importer or your "only representative" must participate in the SIEF

- **Avoid uncoordinated testing**:

  Testing can only be carried out once agreed in the SIEF

  For higher volumes: Before testing can start, Agency must approve testing proposal

- **Agency helpdesk** addresses questions from outside the EU

- **Substances intended to be released** from articles:

  May also need to be registered

EU Downstream Users: What should they do now?

- Make inventory of your substances and uses
- Communicate up & down the supply chain and outside
  - Approach suppliers about your uses & their possible exposure scenarios
  - Ask your customers about their uses
  - Develop partnerships in your chain and / or with similar users
- Need to apply risk management measures, if you receive Safety Data Sheets
  - Uses must be covered by the Safety Data Sheets!
- In case one wants to keep particular use confidential prepare own Chemical Safety Assessment
  - Check the exceptions to this rule!

Start communication with suppliers and customers!

Preparing for Chemical Safety Assessment

- What are your uses and what are the identified uses ?
- Exposure scenarios: generic versus specific / narrow?
  - Need to be sufficiently specific
    in order to communicate appropriate risk management measures
  - Specific scenarios cost more, but
    may require less testing & less demanding risk management measures
  - Downstream User: do you wish to identify your use or notify yourself?
- Start talking with your suppliers and customers today!
- Co-operate within business associations
- Explore the possibilities in the Regulation
  and choose the option that fits best!

The development of Exposure Scenarios requires dialogue and cooperation within the supply chain

Where to turn for help?

1. Check the legislation (available in all EU languages) (http://eur-lex.europa.eu/JOHtml.do?uri=OJ:L:2006:396:SOM:EN:HTML)
2. Check the Guidance website (available as from June 2007; in the meantime try http://ecb.jrc.it/REACH/)
3. Check the Frequently Asked Questions on the ECHA website (available later in 2007; in the meantime try http://ec.europa.eu/enterprise/reach/overview_en.htm)
4. Talk to your colleagues, business associations, industry helpdesks
5. Contact your national helpdesk (as of 1 June 2007; in the meantime check with competent authorities or the Commission)

Many tools will become available after entry into force – thank you for your patience

Further Information

Further information is available on the internet pages of the Commission:

http://ec.europa.eu/enterprise/reach/index_en.htm

http://ec.europa.eu/comm/environment/chemicals/reach.htm

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