European Chemicals Agency & European Chemicals Legislation

Visit of the delegation from Brazilian Ministry of Environment & Institute of Environment and Renewable Natural Resources to ECHA

15 April 2013, Helsinki

Petteri Mäkelä

ECHA – six years old and growing

- Started on 1 June 2007
- Over 500 staff from 27 countries

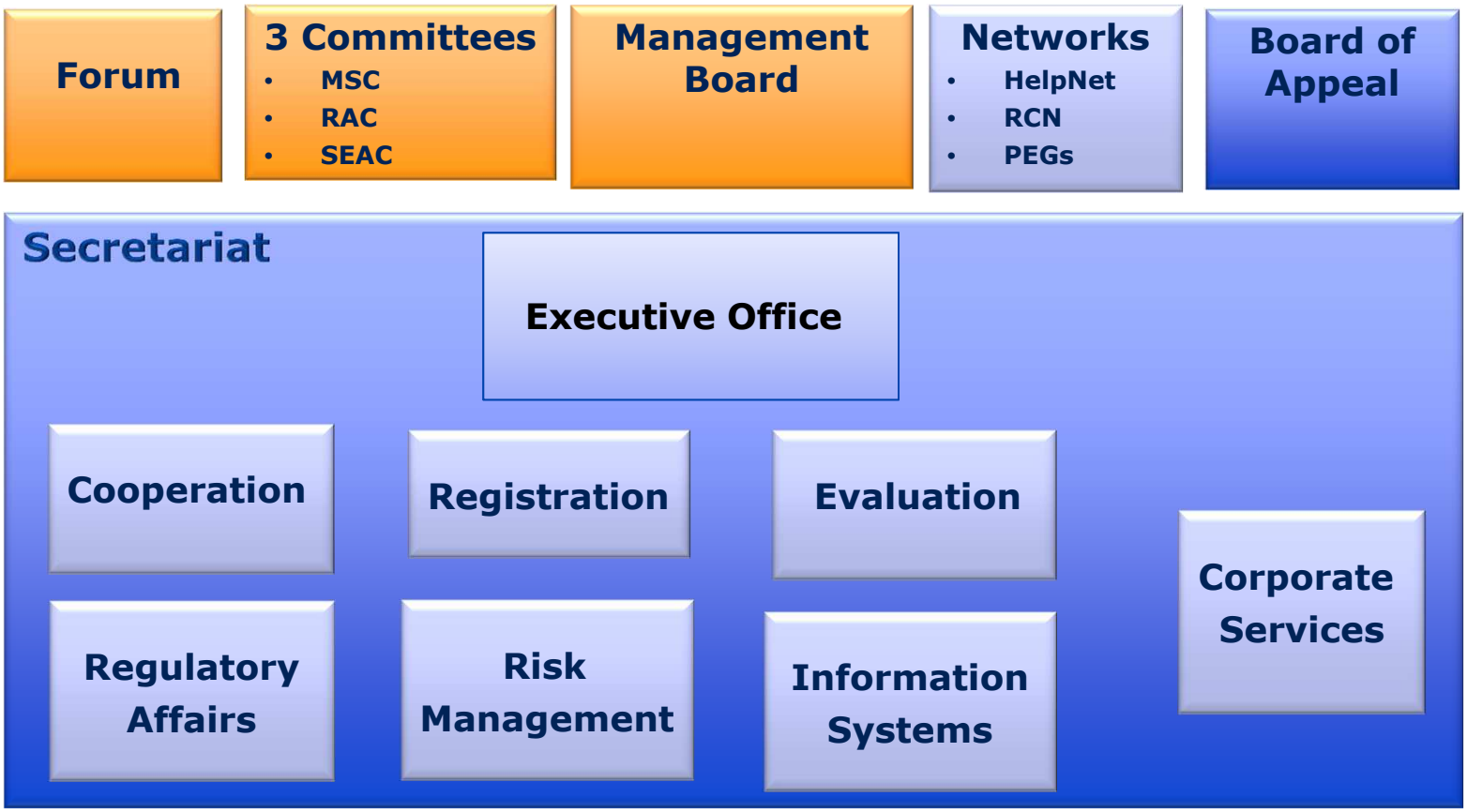
- Originally REACH
- Since 2009 Classification and Labelling
- Now also Biocides and PIC

Our mission

Driving force in implementing EU's chemicals legislation for the benefit of human health and the environment as well as competitiveness and innovation

- Help companies to comply
- Advance the safe use of chemicals
- Provide information on chemicals
- Address substances of concern

ECHA - Organisation



ECHA
EUROPEAN CHEMICALS AGENCY

REACH & CLP – 30 Countries

What did we do in 2012?

Lots of very visible achievements

- Updates of **IT tools and guidance** ready for 2nd deadline
- Deadline met for all **testing proposals** from 1st deadline
- **Candidate List** of 136 substances
- On target with **Biocides/PIC** recruitment & preparations
- Agreed with MB on **strategic objectives** & outline for MAWP

Challenges 2013

- Peak year for REACH:
  - 2nd registration deadline and its implications
  - 5 % compliance check target
  - Substance evaluation
  - First authorisation applications
- Biocides Entry into Operation under threat
- Need to focus on WP priorities and strategic objectives and be ever more efficient

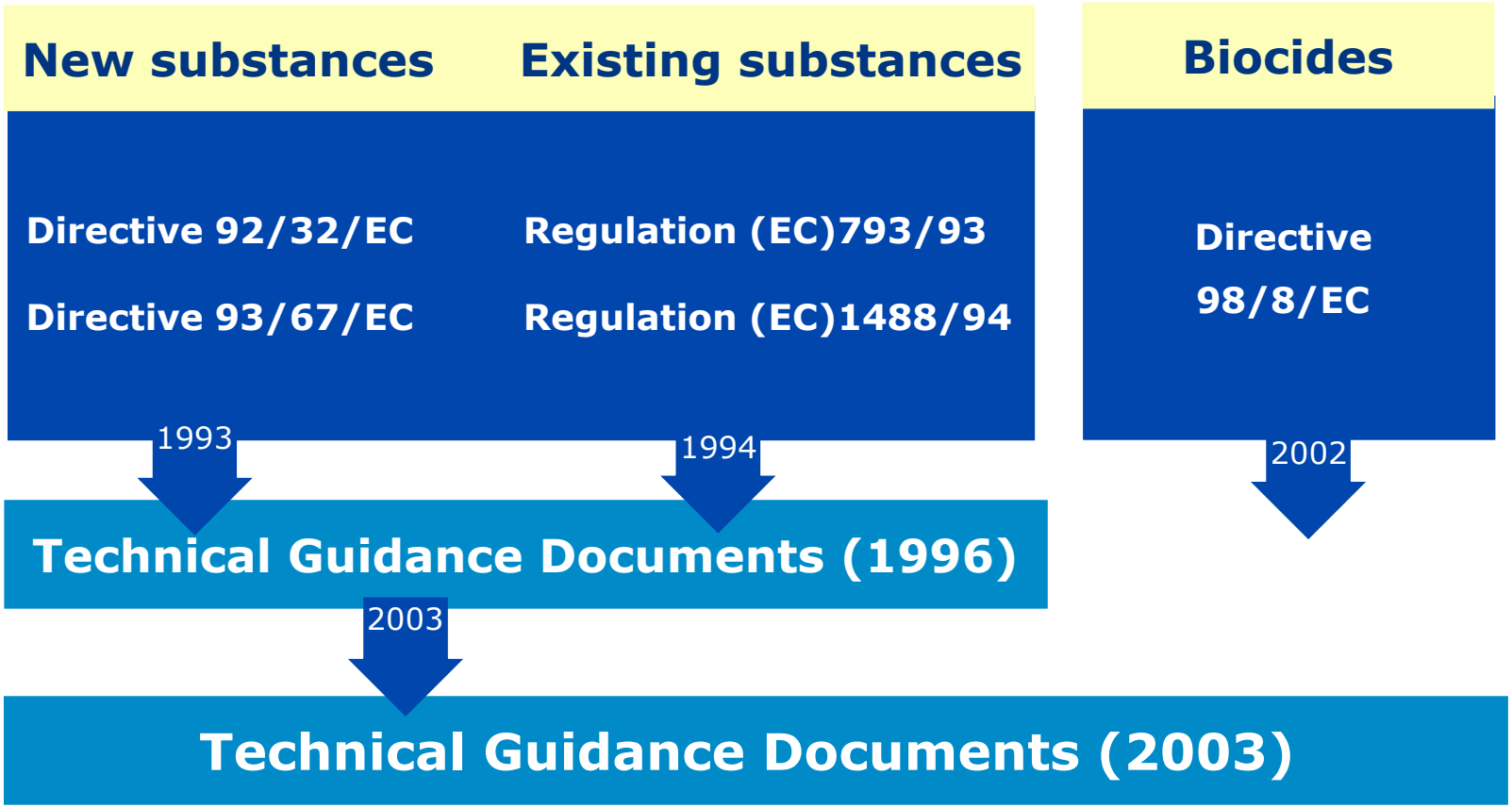
ECHA's Strategic objectives

- Getting better **quality data** from industry
- Using data intelligently for identifying and addressing **chemicals of concern**
- Becoming the **regulatory science** hub
- Using **resources** efficiently and effectively

ECHA's international activities

1. **OECD-related work**
   - "external aspects" of ECHA work – IUCLID, QSAR toolbox, eChemPortal, expert groups
2. **Support to EU candidate countries**
   - IPA programme and TAIEX
3. **Cooperation with peer regulatory authorities**
   - Memorandum of Understanding: Australia, Canada, Japan & US
4. **Support to European Commission**
   - Multilateral work - UN and other International Conventions
5. **Presentations to third countries**
   - Brazil, China, Korea…

Old legislation



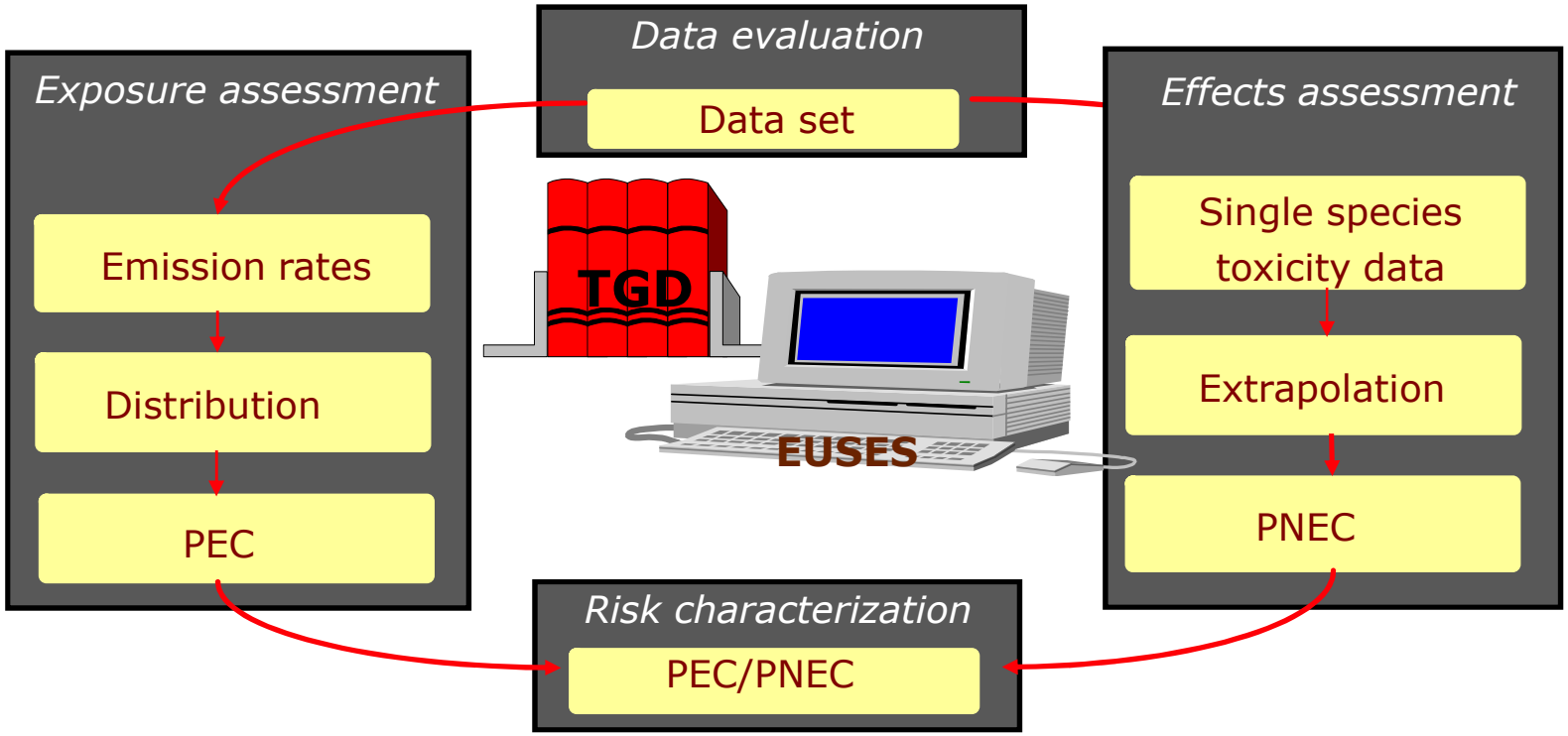
Principles for risk assessment

Detailed procedures for risk assessment are given in the Technical Guidance Documents (TGD):

- Human health
- environment
- QSARs
- emission scenario documents

2nd edition of the Technical Guidance Document (TGD) on Risk Assessment of Chemical Substances following European Regulations and Directives

Risk Assessment Process



Main achievements of old legislation

- **Large data gathering** and summarising process for HPVCs
- Agreement on **RA principles** (TGD/EUSES)
- Agreement on **priority setting** (HERO)
- EU harmonised risk assessments for many controversial substances, forming the **solid basis for EU wide risk reduction measures**

Why new legislation?

Limited knowledge about possible negative effects

Shortcomings of previous chemicals legislation:

- **No obligation** for risk assessment for existing chemicals unless prioritised
- **Data gaps:** 86% of HPVs less than base data
- **Slow and resources intensive** processes
- **Burden of proof** on public authorities
- Actual **uses** of chemicals **unknown**
- Administrative burden **prevented innovation**
- **Complex legal framework:** 40 acts prior to REACH

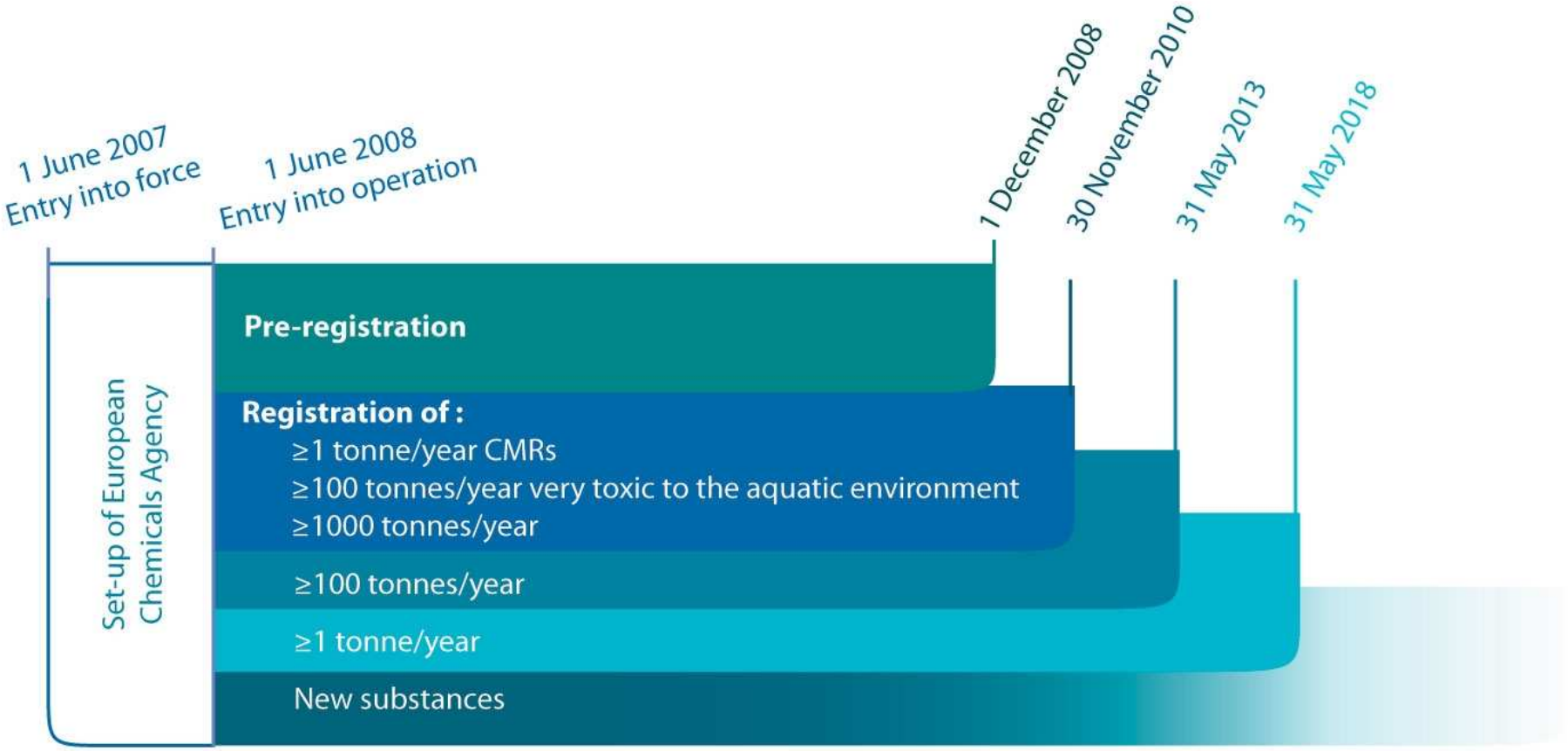
Objectives

1. Protect human health & the environment
2. Promote non-animal testing
3. Enhance the competitiveness
4. Ensure functioning of the internal market
5. Increased transparency
6. Integration with international efforts
7. Conformity with obligations under WTO

New EU Chemicals Legislation

- **REACH:** Registration, Evaluation, Restriction and Authorisation of Chemicals
- **CLP:** Classification, Labelling & Packaging
- **BPR:** Biocides
- **PIC:** Import and Export of Chemicals

REACH Registration deadlines



Roles - industry

- Pre-registration
- Data sharing
- Registration
- Self-Classification
- Notification to C&L Inventory
- Authorisation application

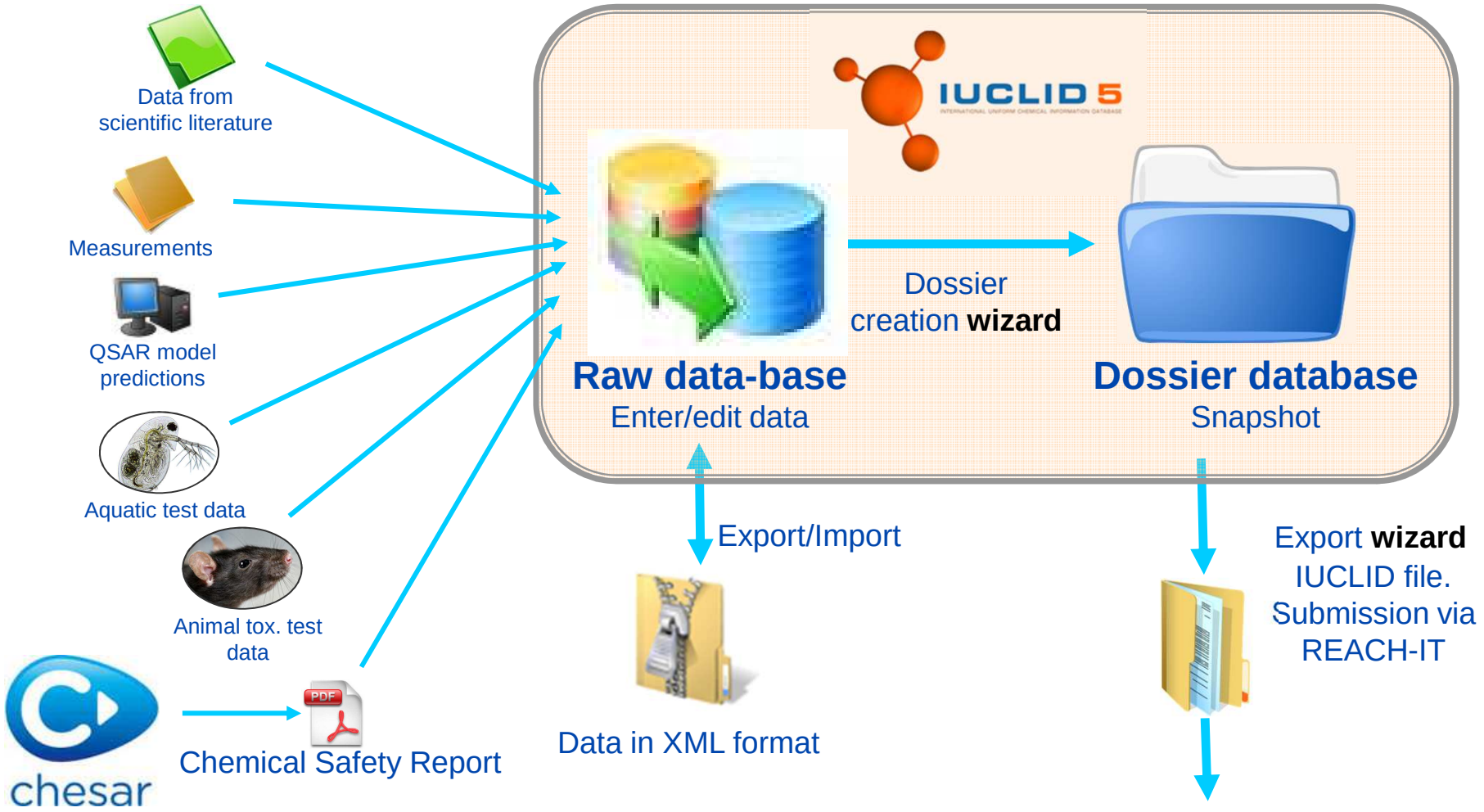
Roles - Authorities

- Dossier evaluation - ECHA
  - Evaluation of testing proposals
  - Compliance checks
- Substance evaluation - Member States
  - Authorisation / restrictions / harmonised classification & labelling
    - Selection of substances for risk management

Roles - EU Commission

- Authorisation / restrictions / harmonised classification & labelling
  - Selection of substances for risk management
  - Decision making

Preparing and submitting dossiers

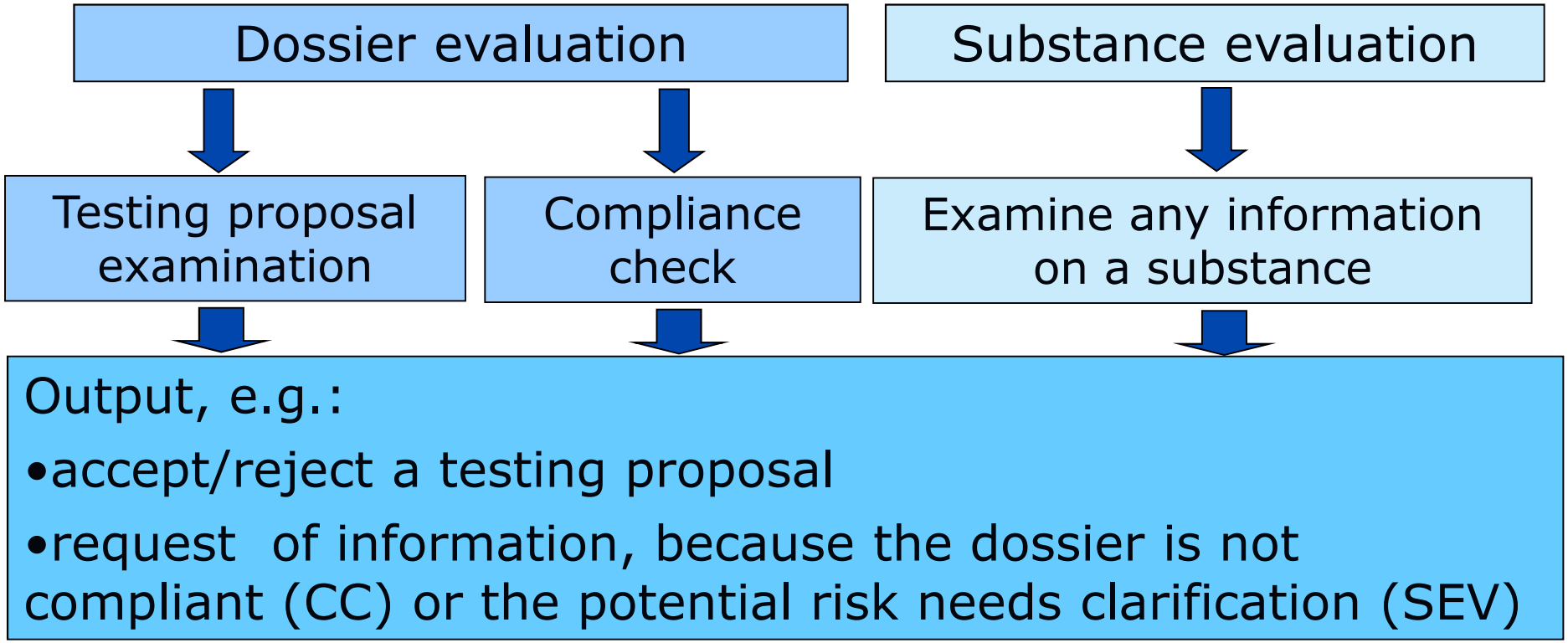


IT tools are essential

Evaluation

ECHA

Member States

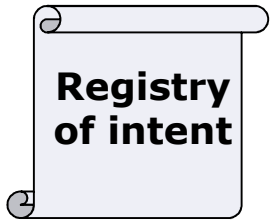


Authorisation

Procedure includes ECHA assessment & public consultations

Step 1

Identification of interest



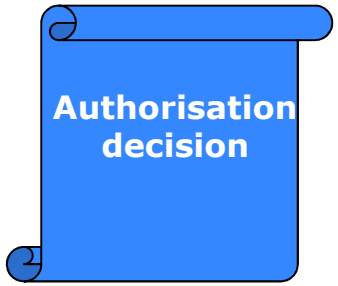
Identification of Substances of Very High Concern

Step 2

Commission decision

Step 3

Granting authorisation

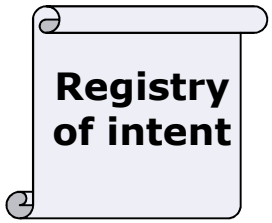


Restrictions / Harmonised C&L

Procedure includes ECHA assessments & public consultations

Step 1

Identification of interest



Step 2

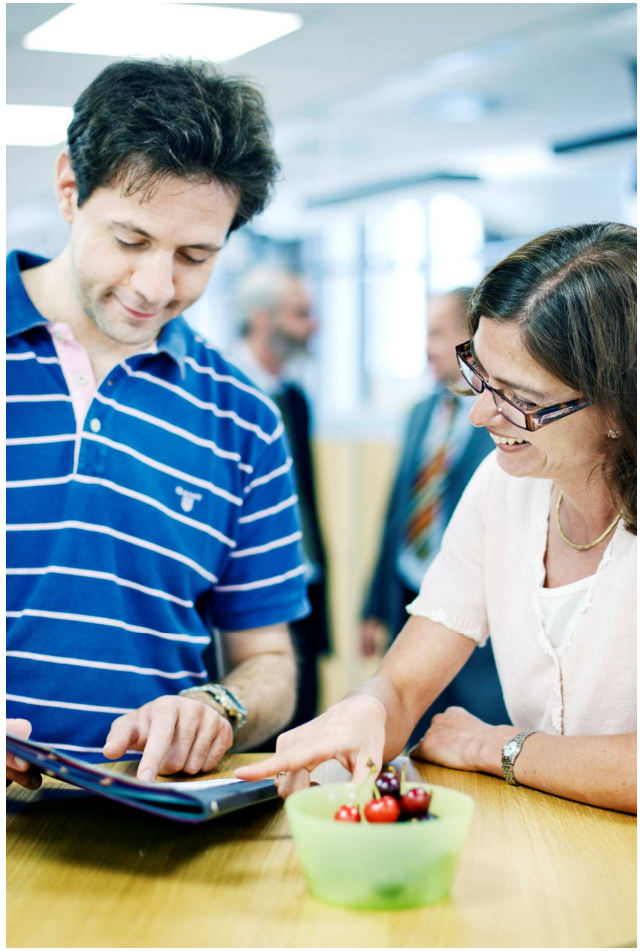
Commission decision

What has changed - Industry

- Clearer roles & responsibilities
- Assessment requirements
- Supply chain communication
- Guidance and IT tools
- Helpdesk support
- Public consultations

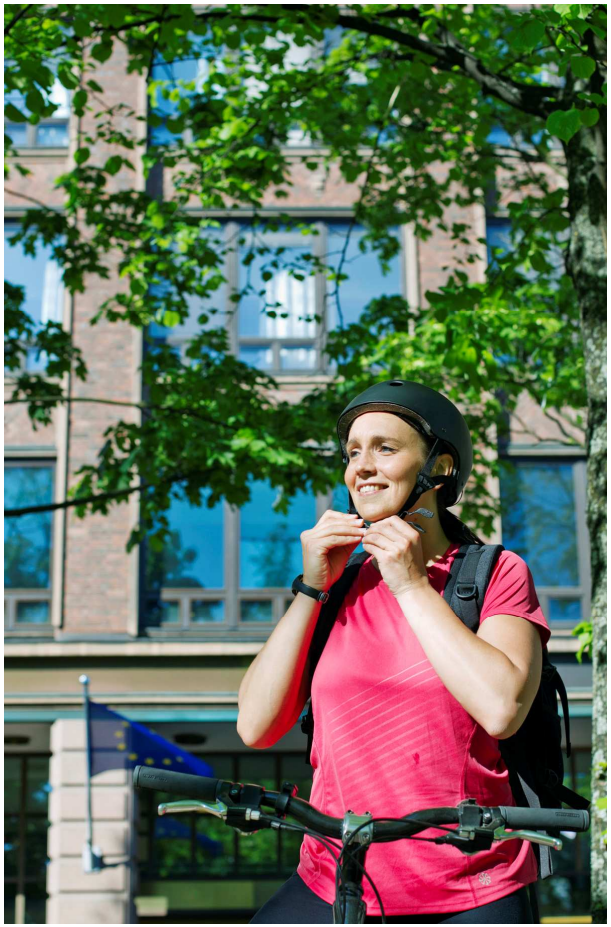
What has changed - Authorities

- Improved data facilitates actions
- Assessment requirements
- Socio-economic analysis
- Reporting and reviews



What has changed - Consumers

- Improved access to information
  - data available online
- Right to request information
  - substances of very high concern in articles
- Safer products
  - more rigorous assessments



Reviews define the future

Title of review	Deadline
ECHA report on operation of REACH	June 2011
Review of ECHA	June 2012
Low tonnage review	June 2012
Review of the scope of REACH	June 2012
Commission REACH review report	Jun 2012 > Feb 2013
Review of the fee regulation	January 2013
Endocrine disrupters review	June 2013
Review of the fee regulation	January 2013
Review of CSA obligations	June 2014 - for CMRs cat. 1a, 1b
Review of CSA obligations	June 2019 - for other substances
Review of Article 33	June 2019
Review of testing requirements	June 2019
Review of polymers	Not specified
Review of the Board of Appeal regulation	Not specified