Classification & Labelling and ECHA Support to Industry

The Latest Trends in the EU Chemicals Management: REACH, CLP & BPR

Petteri Mäkelä

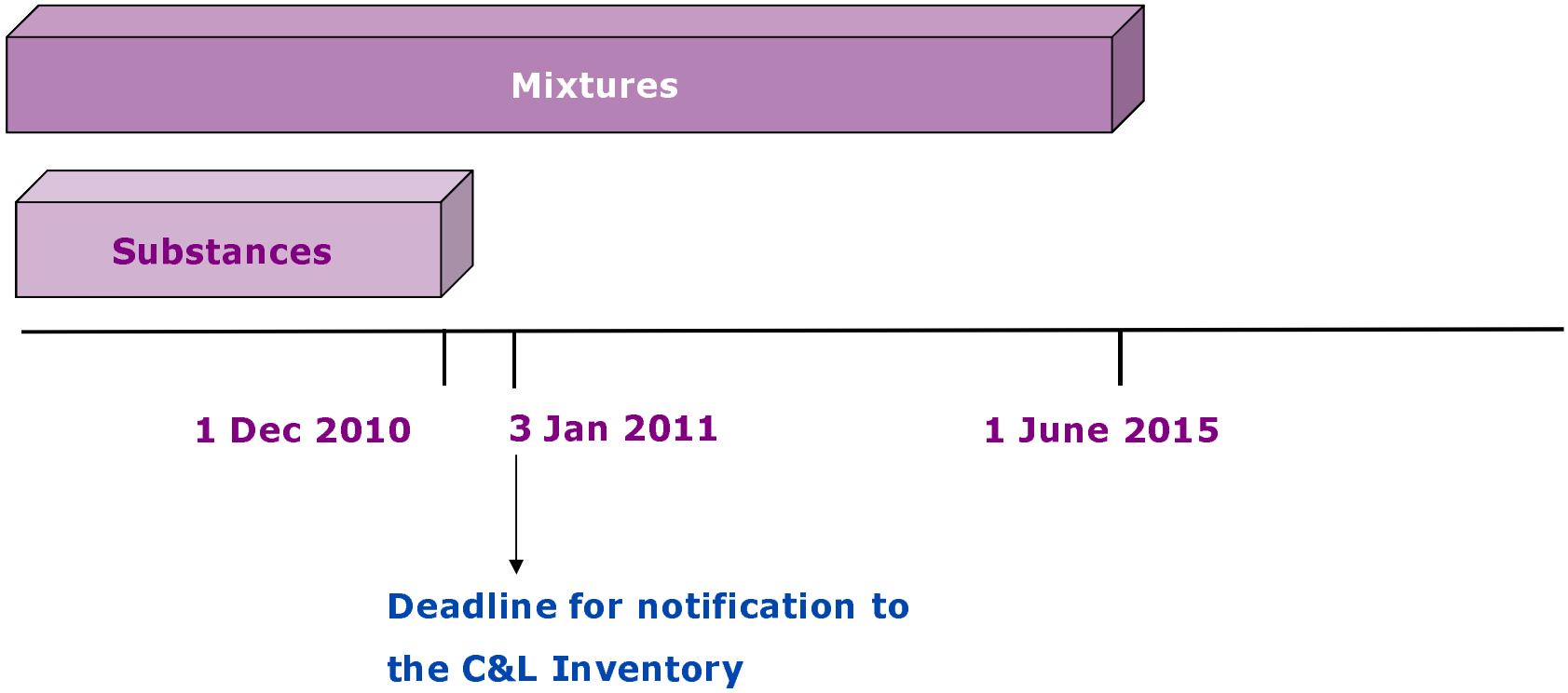
CLP Regulation

- **C**lassification
- **L**abelling
- **P**ackaging of substances & mixtures

CLP entered into force in January 2009

Introduces the GHS criteria in the EU

CLP transitional periods



ECHA's main tasks under CLP

- **Classification and Labelling Inventory**
  - Notifications on self-classifications of hazardous substances on the EU market
- Proposals for **Harmonised Classification and Labelling** (CLH)
  - Risk Assessment Committee
- Applications for **Alternative chemical names for substances in mixtures**
  - Formulators of mixtures apply for use of alternative names for hazardous substances on labels and safety data sheets

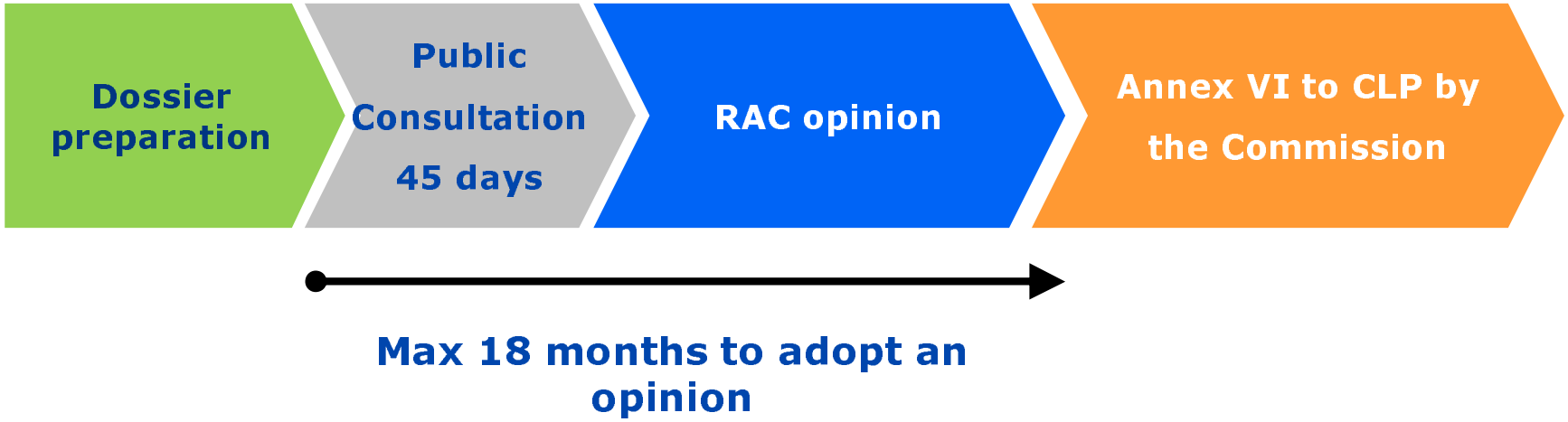
Harmonised Classification & Labelling

- Harmonisation of classification at **EU-level**
- CLP Regulation focuses on substances which are of most concern to humans
  - Carcinogenic (C)
  - Mutagenic (M)
  - Reproductive toxicants (R)
  - Respiratory sensitisers (RS)
- **Active substances** in plant protection products (PPPs) and biocidal products (BPs) are normally harmonised

CLH process overview

Main actors

- Dossier submitter (Member states or industry)
- ECHA/RAC
- Parties Concerned
- European Commission



Harmonised C&L - status

- ~100 RAC opinions adopted
- ~100 CLH proposals under processing
- Annex VI to CLP
  - Over 4,000 entries
  - New entries included by Adaptation to technical progress (currently three ATPs)

Classification and Labelling Inventory

Manufacturers/Importers are obliged to notify

- All hazardous substances (under CLP), and
- All substances subject to REACH registration…

…which are placed on the market

Notifications should contain

- Substance Identity
- Classification and Labelling according to CLP

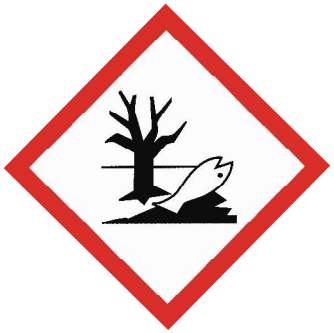
ECHA

- maintains a public **classification and labelling inventory** in the form of a database

Classification and Labelling Inventory

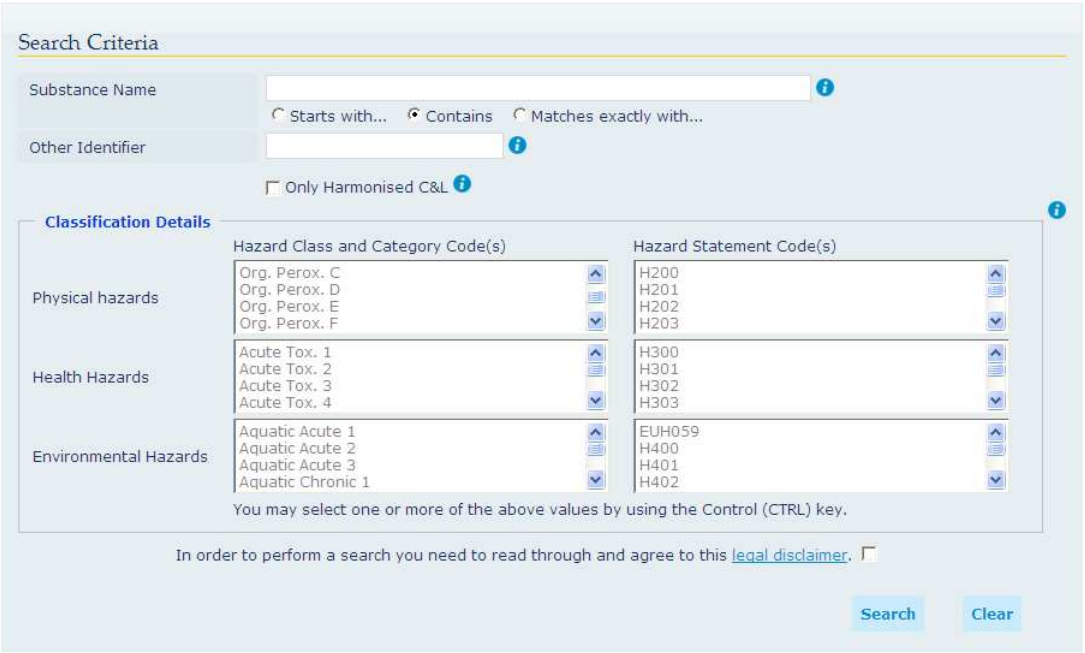
- **Notifications to the C&L Inventory**
  - Currently over **6 million** notifications for over 120,000 substances

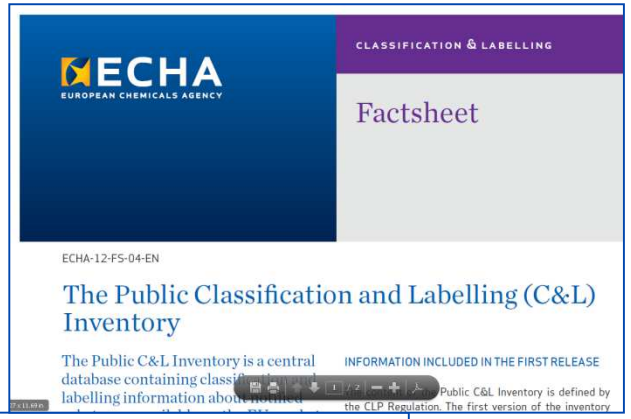
- **C&L Inventory available since Feb 2012:**
  - Up-to-date information on the substances on the EU market



Public Classification & Labelling inventory

Contains information on 110,000 substances





- Includes **self classification & labelling** information on **notified substances**

Notified classification and labelling

General Information

EC Number	CAS Number	IUPAC Name
200-262-8	56-23-5	Methane, tetrachloro-

Notified classification and labelling according to CLP criteria

Classification		Labelling			Specific Concentration limits, M- Factors	Notes	Number of Notifiers	Joint Entries	View
Hazard Class and Category Code(s)	Hazard Statement Code(s)	Hazard Statement Code(s)	Supplementary Hazard Statement Code (s)	Pictograms Signal Word Code (s)					
Ozone 1	EUH059		EUH059	GHS06 GHS08 Dgr	STOT RE 1: C ≥ 1% STOT RE 2: 0,2% ≤ C < 1%		83		
Acute Tox. 3	H301	H301							
Acute Tox. 3	H311	H311							
Acute Tox. 3	H331	H331							
Carc. 2	H351	H351							
STOT RE 1	H372	H372							
Aquatic Chronic 3	H412	H412							
Ozone 1	EUH059		EUH059	GHS06 GHS08 Dgr	STOT RE 1: C ≥ 1% STOT RE 2: 0,2% ≤ C < 1%		55	✔	
Acute Tox. 3	H301	H301							
Acute Tox. 3	H311	H311							
Acute Tox. 3	H331	H331							
Carc. 2	H351	H351							

- And on **harmonised entries** according to CLP Regulation

Summary Of Classification and Labelling

Harmonised classification - Annex VI of Regulation (EC) No 1272/2008 (CLP Regulation)

General Information

EC Number	CAS Number	Index Number	International Chemical Identification
200-262-8	56-23-5	602-008-00-5	tetrachloromethane carbon tetrachloride

ATP Inserted / Updated: CLP00/ATP02

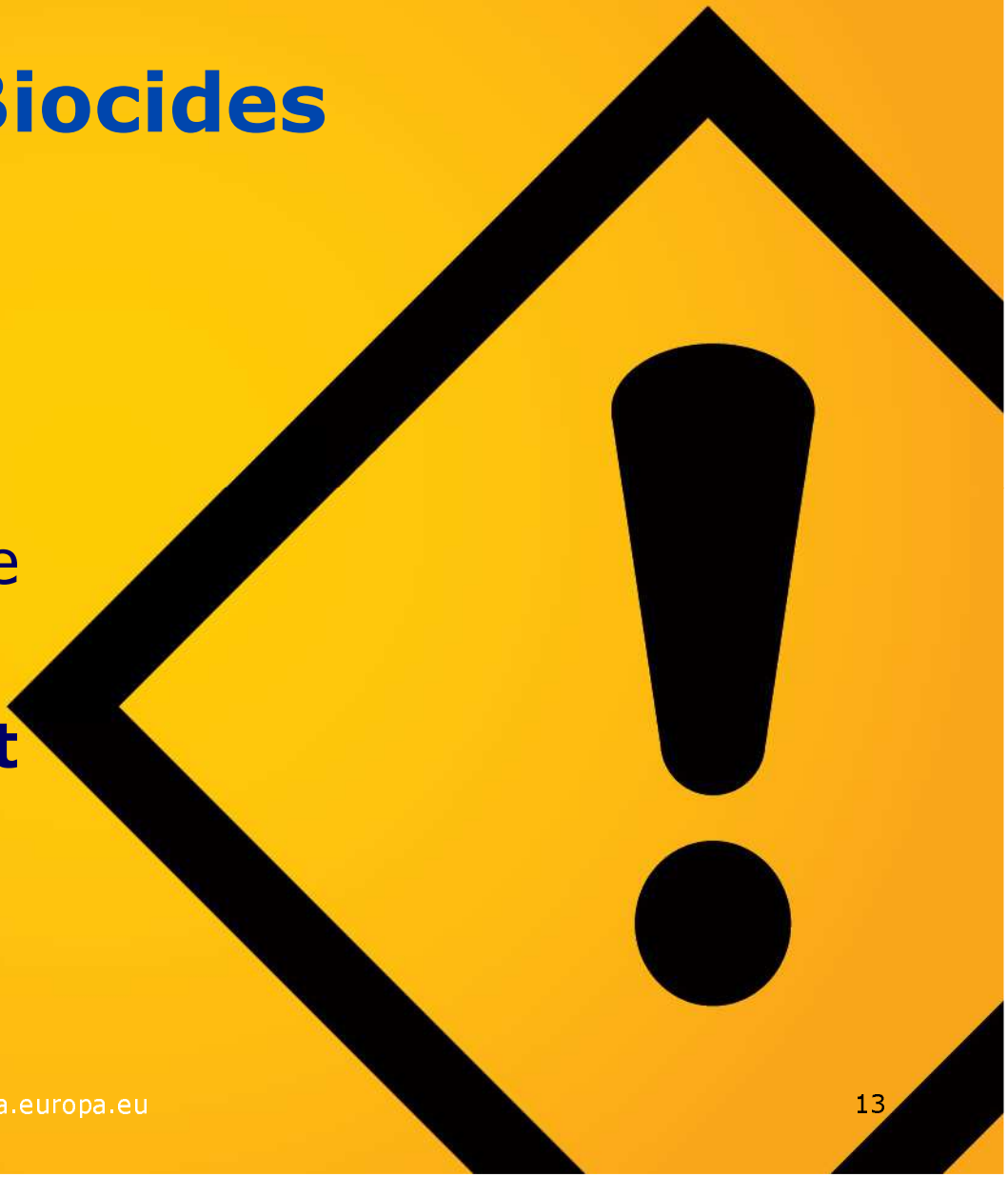
CLP Classification (Table 3.1)

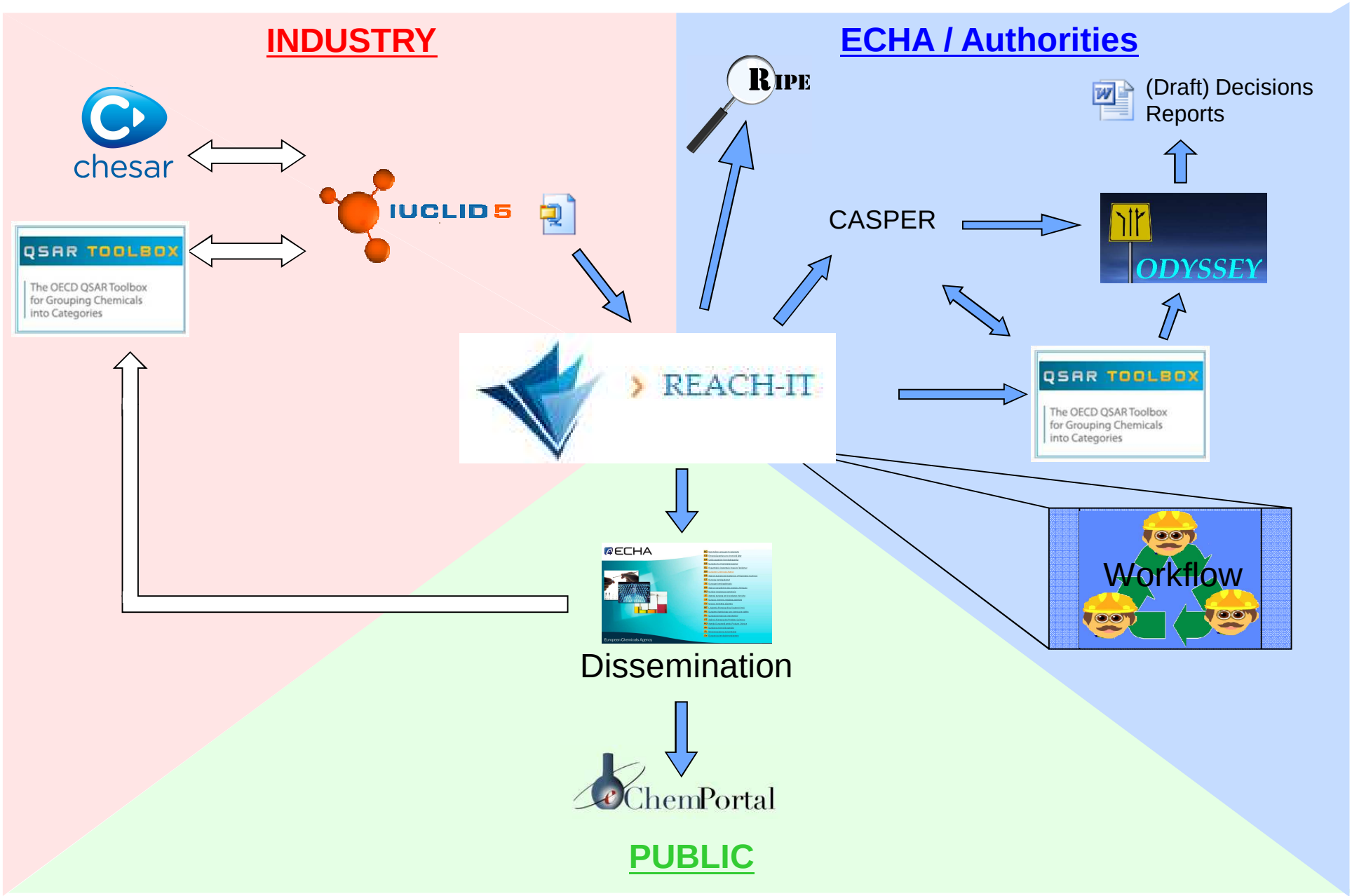
Classification		Labelling			Specific Concentration limits, M-Factors	Notes
Hazard Class and Category Code(s)	Hazard Statement Code (s)	Hazard Statement Code (s)	Supplementary Hazard Statement Code(s)	Pictograms, Signal Word Code(s)		
Acute Tox. 3 *	H301	H301		GHS06 GHS08 Dgr	* STOT RE 1; H372; C ≥ 1% STOT RE 2; H373; 0,2% ≤ C < 1%	
Acute Tox. 3 *	H311	H311				
Acute Tox. 3 *	H331	H331				
Carc. 2	H351	H351				
STOT RE 1	H372 **	H372 **				
Aquatic Chronic 3	H412	H412				
Ozone 1	H420	H420				

Signal Words	Pictograms	
Danger		
	Skull and crossbones	Health hazard

REACH, CLP & Biocides

- Require ECHA to provide:
  - **technical and scientific** guidance and tools
  - **Helpdesk support**
  - **explanatory information**




INDUSTRY
ECHA / Authorities
chesar
IUCLID 5
QSAR TOOLBOX
The OECD QSAR Toolbox for Grouping Chemicals into Categories
RIPE
(Draft) Decisions
Reports
CASPER
ODYSSEY
REACH-IT
QSAR TOOLBOX
The OECD QSAR Toolbox for Grouping Chemicals into Categories
Workflow
ECHA
Dissemination
eChemPortal
PUBLIC

IUCLID 5

- IT application to **collect, store & exchange** information on chemicals
- Designed to serve REACH & other regulatory programmes
  - OECD HPV Chemicals
  - EU Biocidal Products
- **Key tool** for industry in submitting data to ECHA

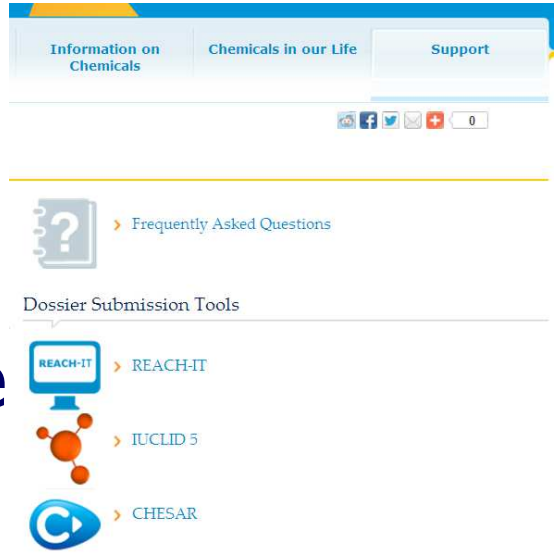
Website:
www.iuclid.eu

Where to get IUCLID

Available **free** of charge on the IUCLID 5 website at:

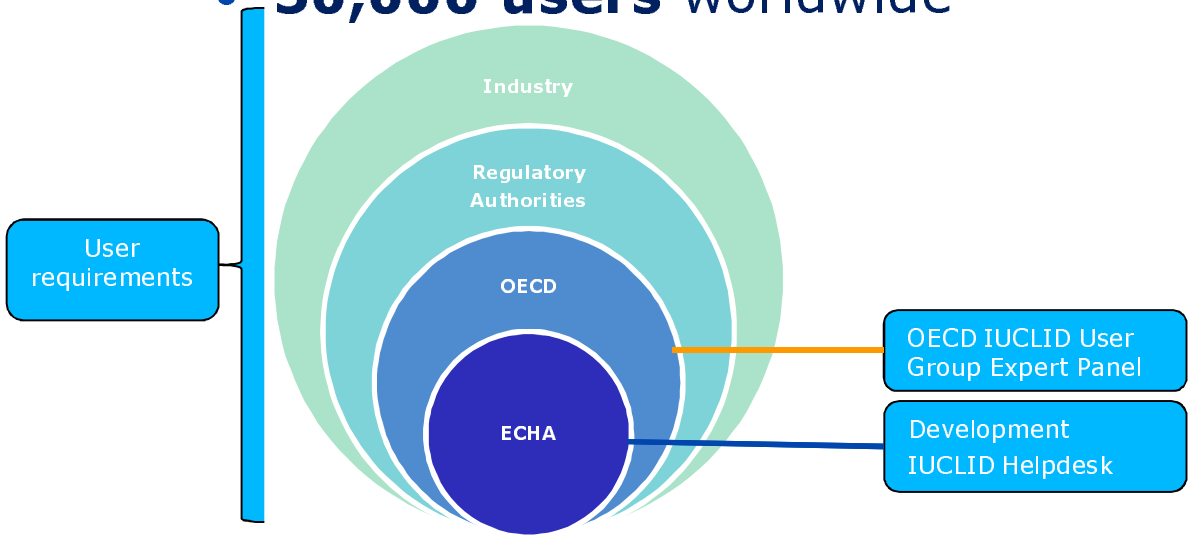
http://iuclid.eu

Accessible via the ECHA website



ECHA makes its work available globally

- **IUCLID**
  - Developed in coordination with OECD to promote global use
  - Core: **OECD Harmonised templates** for reporting chemical properties in a standard way and ensuring data exchange
  - **50,000 users** worldwide

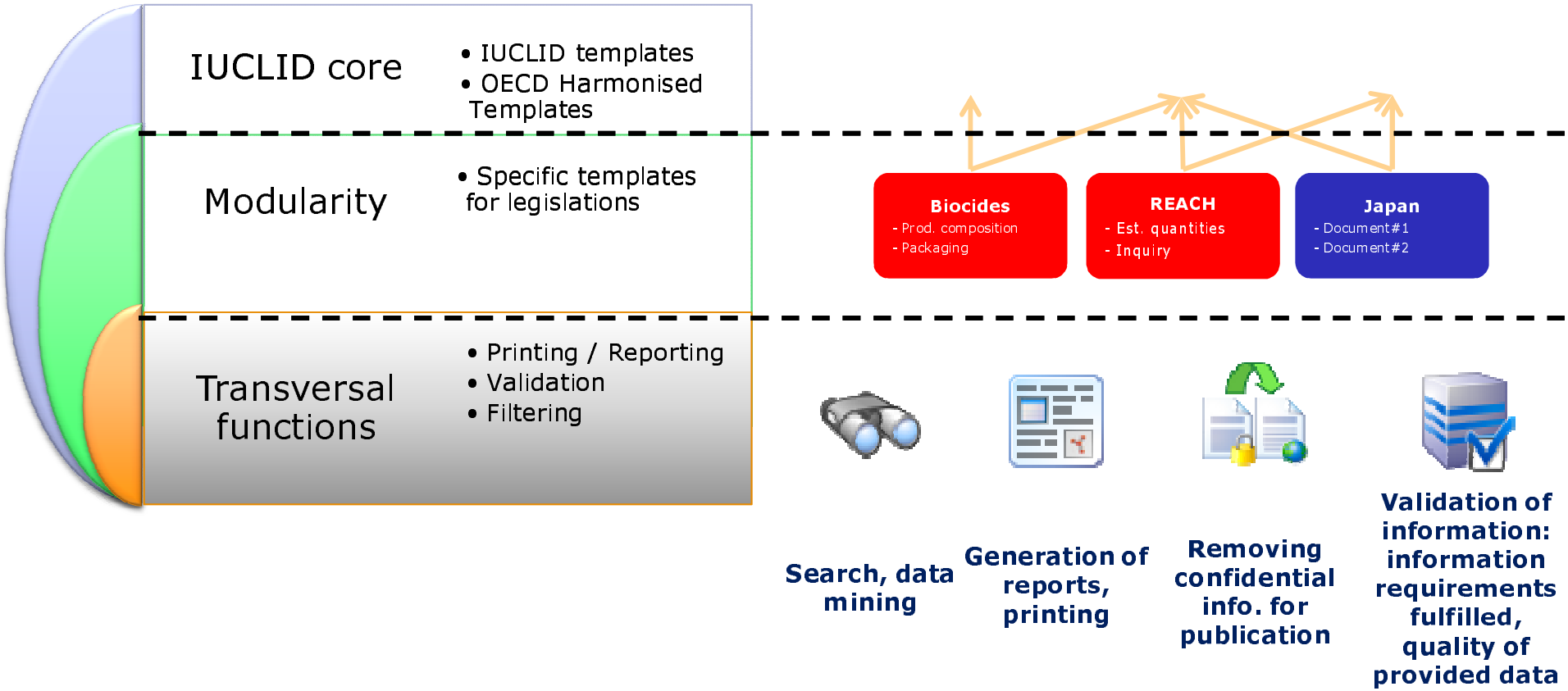


IUCLID 5 is used for different **chemical programmes**, e.g.

- OECD HPVC Program
- US HPV Challenge Program
- Japan HPV Challenge Program
- Swiss new chemicals notification
- EU Biocidal Products Regulation
- EU REACH
- EU CLP

In progress: IUCLID 6

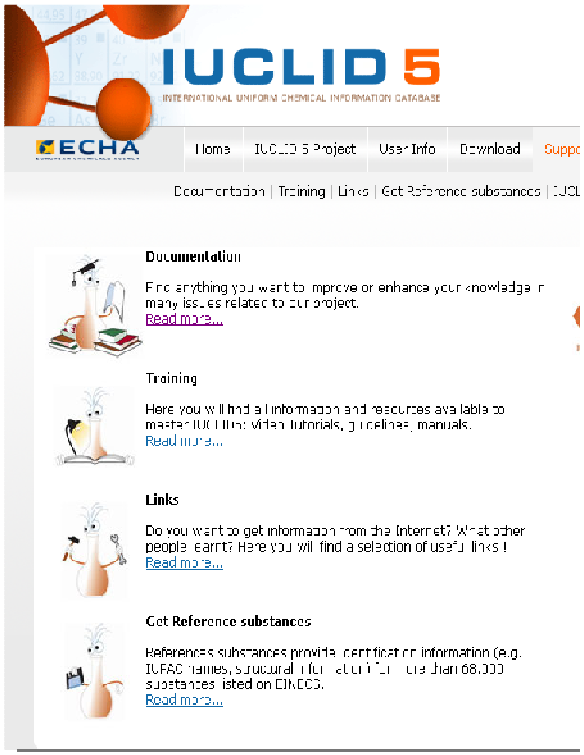
Concept



REACH plug-ins

- Technical completeness check
- Fee calculation
- Dissemination
- Chemical safety report
- Dossier Quality Assistant

Where to get support?

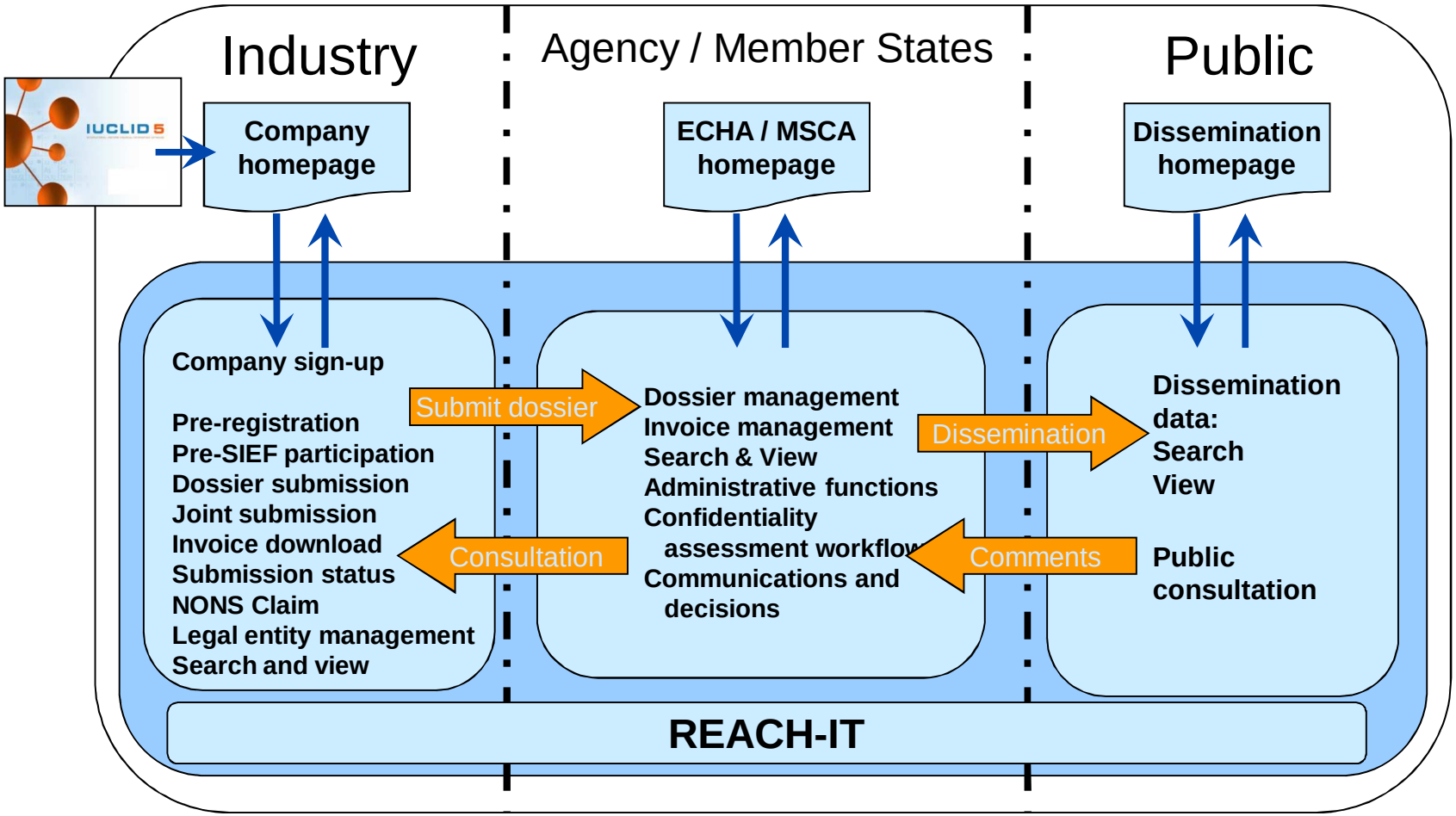


Support section on IUCLID 5 website

REACH-IT

- Web based application
- Ensure IT-support for the implementation of the new EU chemicals legislation
- Daily workflow in ECHA and Member States
- The main objectives:
  - Enable ECHA to receive, process and store **dossiers** and **payments**
  - Enable the **dissemination** of non-confidential registration dossier data and other relevant data

REACH-IT Overview



CHESAR

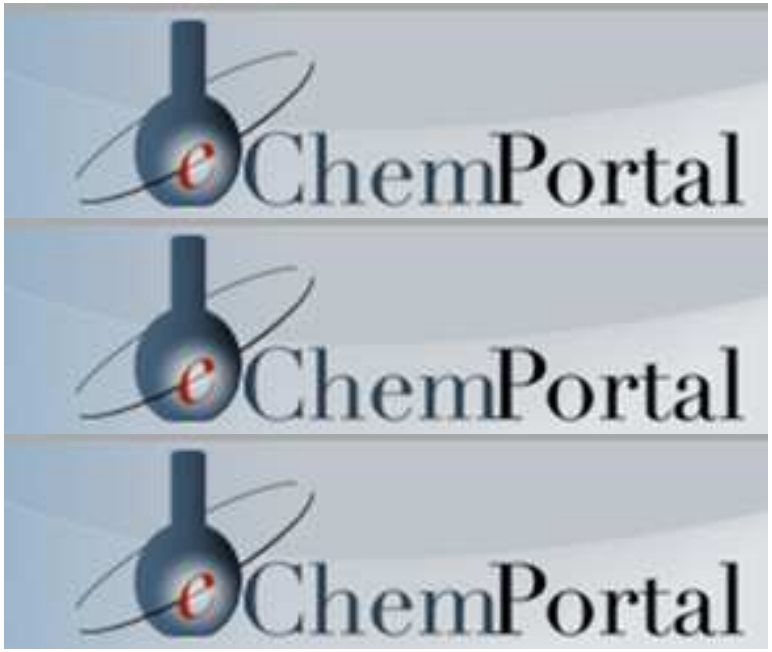
(CHEmical Safety Assessment and Reporting tool)

- Purpose:
  - REACH requires ECHA to support registrants for preparing their CSR
- Links to:
  - IUCLID
- Users:
  - Registrants

www.chesar.echa.europa.eu

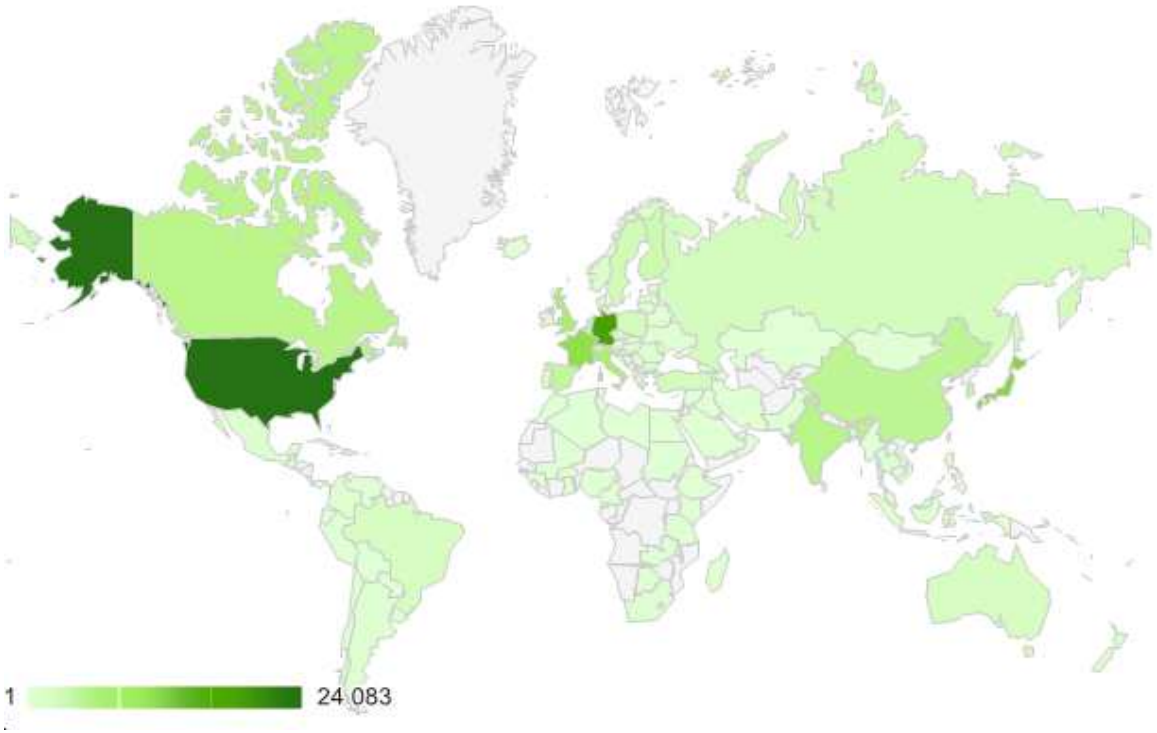
eChem portal

- OECD project
- Free public access to information on chemicals
- Search simultaneously multiple databases around the world



Global Use of eChemPortal

The top ten visitors are: USA, Germany, Japan, France, UK, Italy, India, Canada, China and South Korea



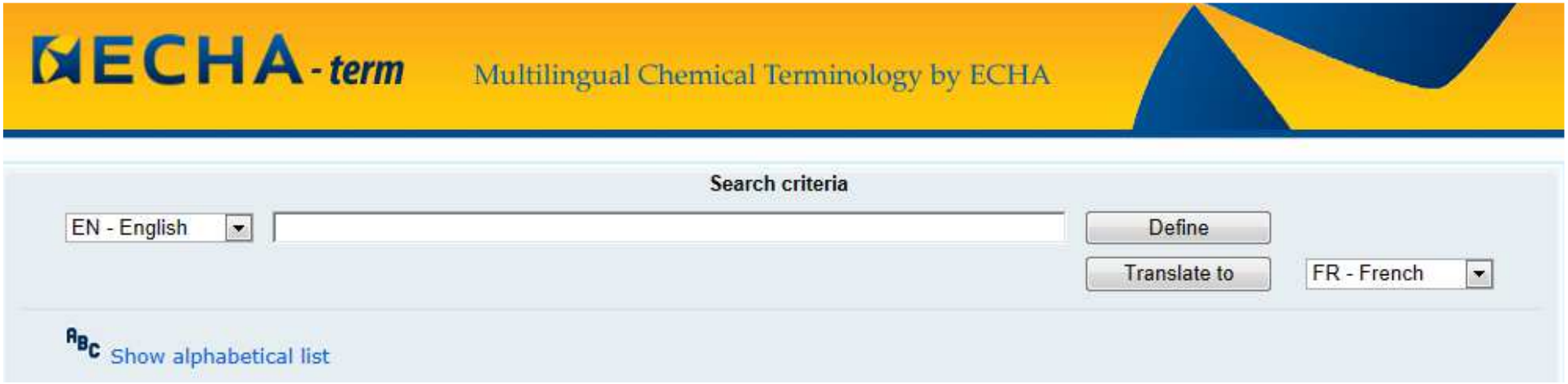
QSAR Toolbox

- Purpose:
  - Software for grouping chemicals into categories and filling (eco)toxicity data gaps for assessing the hazard of chemicals
- Links to:
  - IUCLID; upload of own experimental databases possible
- Users:
  - ECHA, industry, authorities …

www.qsartoolbox.org

Navigator

- Helps industry to determine its **obligations** under REACH
- Find the appropriate **guidance** on how to fulfil obligations
- Updated when Guidance is updated
- A Navigator session applies to a **specific substance**



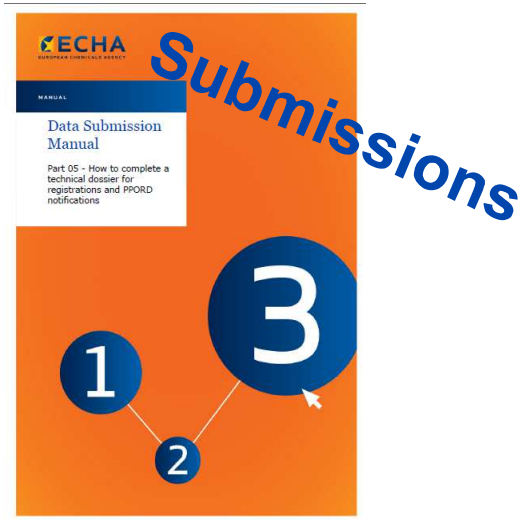
- REACH, CLP & BPR
  - terms and definitions
  - 22 languages
- Search & consultation
- Around 1,000 entries
- Data export possible

- Users in 60 countries around the globe
- Typically 350 queries/d
- > 600 registered users

http://echa.cdt.europa.eu

ECHA Helpdesk

REACH & CLP



Submissions

ECHA Helpdesk

Assisting companies: Regulatory/technical advice

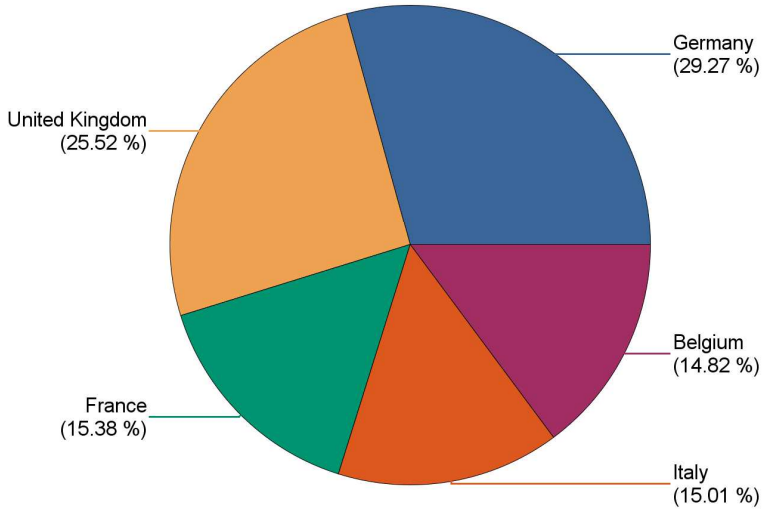
1st level
The Helpdesk Unit takes care of all questions

2nd level
ECHA experts contribute to answering questions, if needed

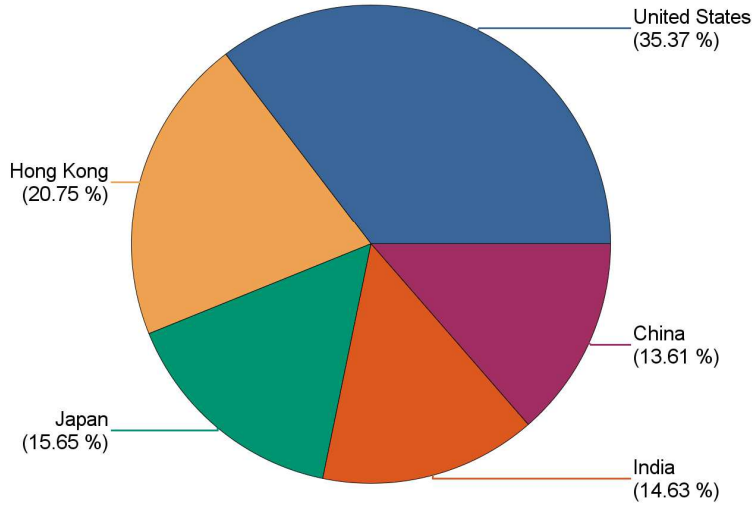
3rd level
COM provides legal interpretation and the external IT service provider fixes bugs as the last resort

ECHA Helpdesk Statistics

Top EU/EEA countries (100 %)



Top non-EU/EEA countries (100 %) *

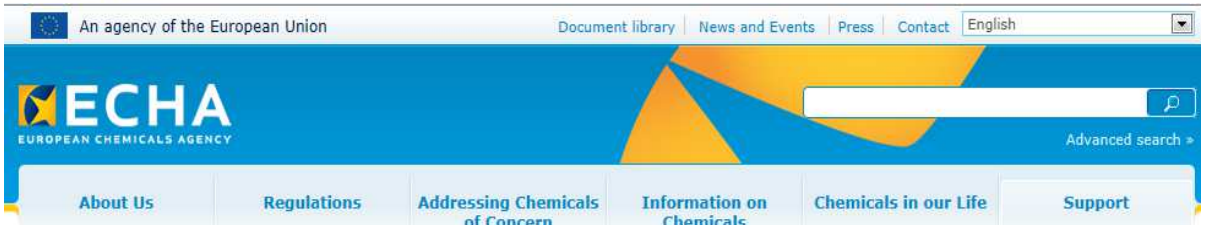


*** And territories**

Guidance

- Assist stakeholders in implementing their obligations – but not legally binding
  - Developed with stakeholders to ensure broad support of all important players
  - Documents are updated
- Shows the "safest" way for industry to fulfil their obligations

ECHA
EUROPEAN CHEMICALS AGENCY



ECHA Actively Support Duty Holders

Support

This section of the website provides tools and practical guidance to companies which have responsibilities under the EU chemicals legislation.

REACH

- Guidance documents
- Identify your obligations
- Practical examples of exposure scenarios
- Information Toolkit
- Information for registrants
- Restriction
- Authorisation
- Socio-economic analysis in REACH
- Small and Medium Enterprises

CLP

- Guidance documents
- CLH
- Small and Medium Enterprises

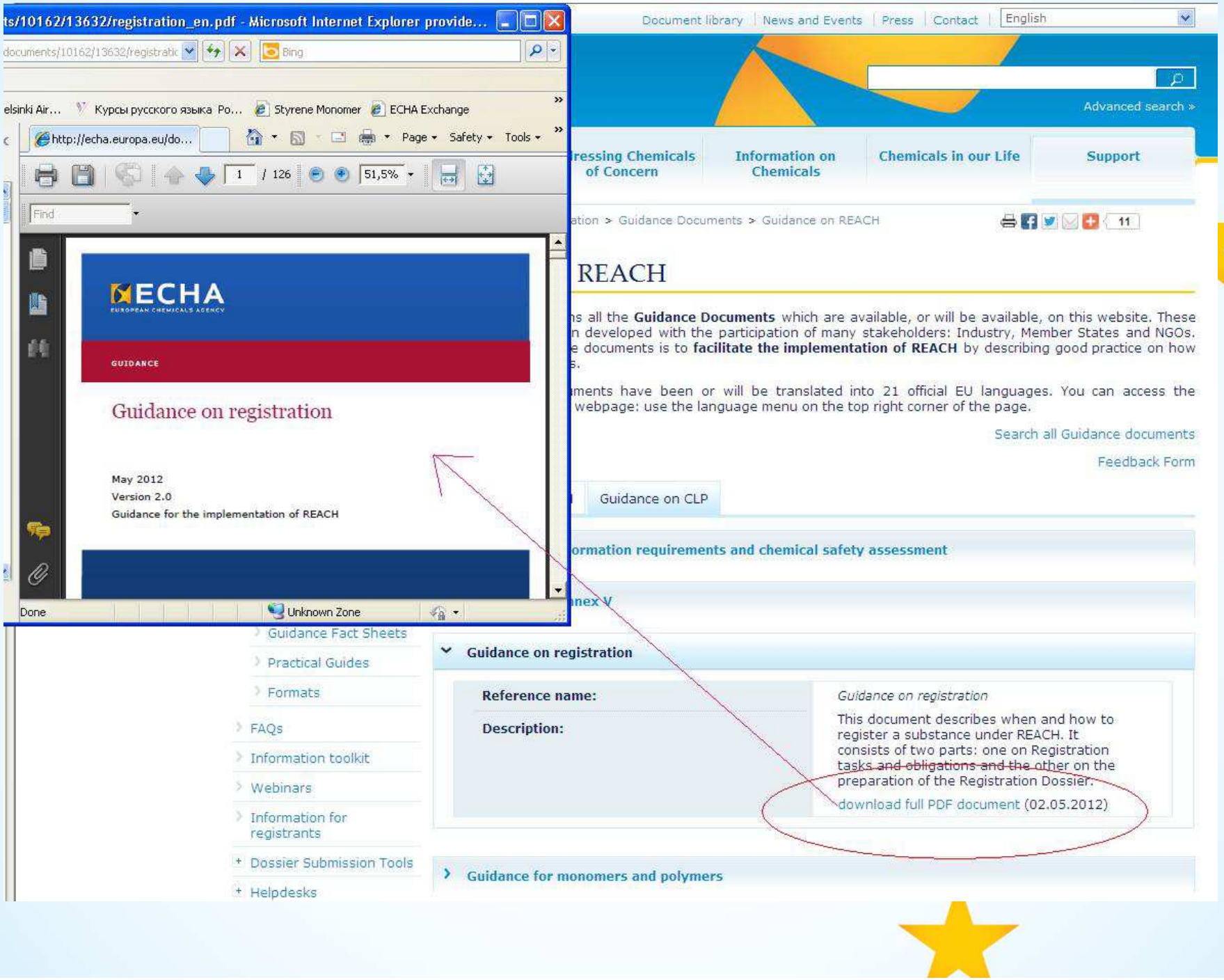
Biocidal Products Regulation

- Guidance documents
- Emission scenario documents
- R4BP 3
- Small and Medium Enterprise

- Publications
- Document library
- ECHA Helpdesk
- National Helpdesks
- Q&As Support
- Webinars

Dossier Submission Tools

- REACH-IT
- IUCLID 5
- CHESAR
- R4BP 3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GUIDANCE
Guidance on registration
May 2012
Version 2.0
Guidance for the implementation of REACH
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News and Events
Press
Contact
English
Advanced search »
Information on Chemicals
Chemicals in our Life
Support
Guidance Documents > Guidance on REACH
11
REACH
all the Guidance Documents which are available, or will be available, on this website. These developed with the participation of many stakeholders: Industry, Member States and NGOs. documents is to facilitate the implementation of REACH by describing good practice on how
webpage: use the language menu on the top right corner of the page.
Search all Guidance documents
Feedback Form
Guidance on CLP
Guidance Fact Sheets
Practical Guides
Formats
FAQs
Information toolkit
Webinars
Information for registrants
Dossier Submission Tools
Helpdesks
Guidance on registration
Reference name:
Description:
Guidance on registration
This document describes when and how to register a substance under REACH. It consists of two parts: one on Registration tasks and obligations and the other on the preparation of the Registration Dossier.
download full PDF document (02.05.2012)
Guidance for monomers and polymers

ECHA
EUROPEAN CHEMICALS AGENCY

Worth to Remember

- **GHS criteria** applies already to substances and start applying to mixtures in 2015
- Over **4,000 substances** have **harmonised** EU C&L
- Public **C&L Inventory** provides information on over 100,000 substances
- **IT is essential** for functioning of the EU chemicals legislation
- ECHA provides **extensive guidance** and **IT tools** free of charge

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Thank you !