

# REACH / European Chemicals Agency databases

*Progress in Global Coordination of Chemical Safety Databases*

SAICM – ICCM2

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# Content

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Main source of information for building  
ECHA databases  
is information submitted by  
EU chemicals companies  
to fulfill their legal requirements  
under the REACH and  
the Classification, Labeling and Packaging (CLP)  
Regulations

- **Registration dossiers**
- **Classification and Labelling notifications**

# REACH: some reminders



- **Principle:** Industry ensures that manufacturing, placing on the market and use of chemicals do not adversely affect human health or the environment:
  - Manufacturers and importers assess their chemicals and document that risks are adequately controlled
  - Manufacturers and importers communicate to downstream users how to control risks
  - Downstream users apply measures to control risks and communicate this further downstream
- Main elements for implementing this principle are **Registration** and **Classification & Labelling** based on the GHS system

# Industry obligations



- **Registration:**
  - Gather and generate data on their substances
  - Use these data to assess the risks
  - Develop & recommend appropriate risk reduction measures
  - Document this information in a **Registration dossier** to be submitted to ECHA by certain deadlines: **2010, 2013, 2018**
- **Pre-registration:** 1 June 2008 – 1 December 2008
  - To benefit from extended deadline for registration
- **C&L notification:** all substances placed on EU market notified to ECHA by 2010

# ECHA obligations



- Establishing and maintaining database(s):
  - with information on all registered substances
  - the classification and labelling inventory
  - the harmonised classification and labelling list
- Information to the public
  - make non confidential information publicly available, free of charge, over the Internet
- Support to Industry
  - specify formats and software packages and make them available on its website for any submissions to the Agency

# Substances concerned

- All substances manufactured or imported in quantities > 1 t/yr per manufacturer or importer:
  - Substances on their own, in mixtures, in articles if intended to be released
- About 30,000 substances concerned
- Focus on priorities:
  - High volumes: (chemicals with greatest)
  - Greatest concern (Carcinogenic, Mutagenic)
- **Regarded as registered**

- **Biocides:** Active substances included in Annex I, IA or IB (98/8/EC) or in the work programme
- **Pesticides:** Active substances included in Annex I (91/414/EEC) or in the work programme for evaluation
- **New substances** notified under 67/548/EEC

# Information requirements for registration

- Identification of the substance
- Manufacture, Uses and Exposure
- Classification & Labelling
- Information on properties
  - Physical chemical properties
  - Environmental fate and behaviour
  - Ecotoxicity and toxicity
- [If > 10 tonnes] Chemical Safety Report
- The higher the tonnage, the higher the information requirements (REACH Annex VII-X)



## IT Tools: IUCLID 5














- One stop shop for collecting, reporting and exchanging data – used by industry and authorities  
<http://iuclid.echa.europa.eu>



- Software application to collect and store information on properties, hazards and uses of chemicals and prepare registration dossiers
- Fully compatible with OECD Harmonised Templates
- Also used for OECD HPV Chemicals Programme and EU Biocides Legislation
- Distributed free on charge
- 25 000 users worldwide

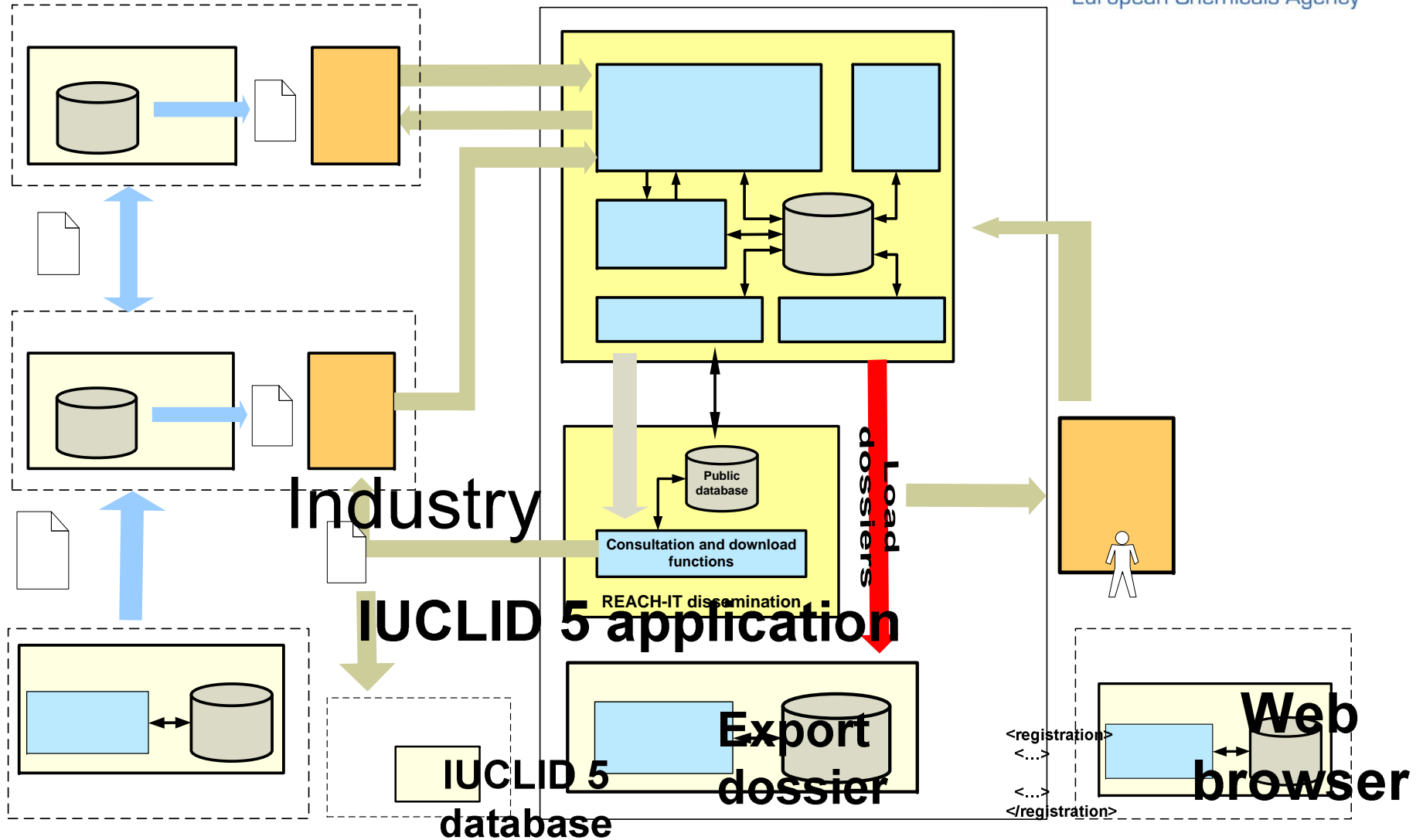
# IT Tools: IUCLID 5

- Information is entered in a **substance dataset**

- +  1 General Information
- +  2 Classification and Labelling
- +  3 Manufacture, use and exposure
- +  4 Physical and chemical properties
- +  5 Environmental fate and pathways
- +  6 Ecotoxicological Information
- +  7 Toxicological information
- .....  8 Analytical methods
- +  9 Residues in food and feedingstuffs
- +  10 Effectiveness against target organisms
- +  11 Guidance on safe use
- +  12 Literature search
- +  13 Assessment Reports

Data  
required  
in  
**REACH**  
Annexes  
VI-X

# The Overall Picture



# ECHA Databases – State of play **ECHA** European Chemicals Agency

- Pre-registration process
  - List of pre-registered substances: 140.000 distinct substances



- EC inventory (more than 100.000), 17.000 identified by CAS numbers, remaining: identified by chemical names or multi-constituent substances
- Publicly available on ECHA website
- Can be downloaded

- Also in the database but not public: for each substance: tonnage range and information on potential registrants (65.000 Legal entities)
- Contact details available only to other pre-registrants of same substance

- Registered substances
  - Substances considered as registered under prior legislation (New chemicals under 67/548/EEC)
    - ca. 8.400 notifications for 5.300 distinct substances
  - Substances registered since 1 June 2008
    - 175 registration received (70% for substances used as intermediates and not placed on the market)
  - Expected in 2010: ca. 25.000 dossiers for ca. 5.000 distinct substances
- (non confidential) information will be published on ECHA web site starting end 2009

# ECHA Databases – State of play ECHA European Chemicals Agency

- Also available on ECHA website:
  - Candidate List of Substances of Very High Concern (SVHC)
    - List of substances which may be prioritised for Authorisation
    - Section “ECHA CHEM”
  - Proposals submitted by EU Member States for:
    - Harmonised Classification & Labeling
    - Identification of SVHC for inclusion on the Candidate List and Recommendations for priority substances for Authorisation
    - Section “Consultations”

## ECHA Databases – Next



- Classification & Labelling Inventory:
  - Publicly available in 2011
- Participation to OECD Global Portal to Information on Chemical Substances (eChemPortal)
  - REACH-IT will be a participating database in 2010
- REACH-IT expected to contain in 2018 information on about 50.000 distinct substances coming from registration dossiers and C&L notifications (based on GHS)

# Global Coordination



ECHA on behalf of the EU Commission contributes to:

- **OECD Harmonised Templates**
  - Contribution to their development
  - Development of XML formats to ensure data exchange between industry and authority IT systems
  - OECD Harmonised Templates are a cornerstone for Global coordination for chemical safety databases
    - Harmonised way to report results of studies on chemicals
    - Facilitate the transfer of data between industry and authorities
    - Major step forward in using same set of data for different regulatory programmes



# Global Coordination



- **IUCLID 5**

- Developed by EU Commission, handed over to ECHA
- **However strong commitment** to develop IUCLID with international partners under OECD coordination to:
  - Support global coordination (IUCLID is fully compatible with OECD Harmonised Templates: easy exchange of data)
  - Support initiatives to implement Chemicals Management systems in countries outside the EU (IUCLID is distributed free of charge – 25.000 organisations using it worldwide)
- Further development coordinated with OECD
- Next: integration of Pesticides Templates

# Global Coordination



- **OECD QSAR Toolbox**

- Contribution to the development of the 2<sup>nd</sup> phase of the Toolbox
- Key for ECHA to build a common framework at international level to generate and evaluate data by using chemical categories or QSARs

- **OECD eChemPortal**

- Contribution to the development of the Portal to enable direct access to properties of chemicals
- ECHA databases will be participating databases when development completed

# Thank you for your attention

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