



**REACH**



# New IT-Trends in Collaboration and Networking for the Process of Registration, Evaluation, Authorisation and Restriction of European Chemicals

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## Unit IV2.1- Information Systems on Chemical Safety

# Agenda



- REACH Regulation, Concept and Timetable
- REACH Implementation Plan
- REACH-IT-Workflows and Functionalities
- Software Application IUCLID 5
- Network Topology and Realization in FEA
- Outlook

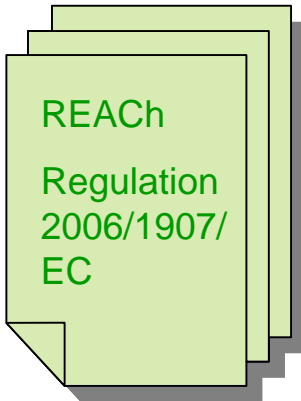


## REACH Regulation 2006/1907/EC



### Greater Responsibility on Industry

- high level of protection of human health and the environment from the risk by chemical substances.
- submit a registration dossier to the **European Chemical Agency (ECHA)** in Helsinki.

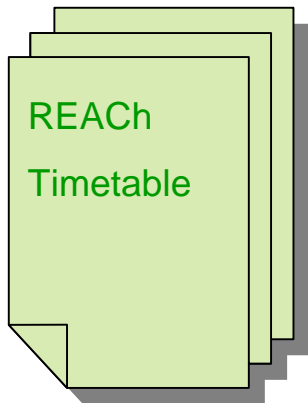




- Risk assessment for human health and the environment (exposure scenarios)
- Conducting Chemical Safety Assessment (CSA)
- Preparing detailed Chemical Safety Report (CSR)

No data – no market!

## REACH Timetable



- **1 June 2007** REACH - Regulation entered into force
- **1 June 2008** Pre-registration period for chemicals started
- **European Chemicals Agency (ECHA)** provided/s information rules, ECHA-WebSide and IT-Tools (**REACH-IT and IUCLID 5**)
- **1 December 2008** Pre-registration period ended
- **1 January 2009** ECHA published list of pre-registered substances
- **1 December 2010** Registration deadline for phase-in substances manufactured or imported 1,000 tonnes + per annum

# REACH Implementation Plan

## RIP 2.1 REACH-IT



### REACH Regulation, Article 111

„**Formats and software for submission of information to the European Chemical Agency**“

*"The Agency shall specify **formats** and make them available **free of charge** [...] on its website*

*Member States, manufactures, importers, distributors or downstream users **shall use these formats** [...]*

*[..] the format of the technical dossier [...] **shall be IUCLID.***

*The Agency shall coordinate the further development of this format with the Organisation for Economic Cooperation and Development (OECD) to ensure **maximum harmonisation.**"*

# Two Main IT-Systems



## REACH-IT:

- Support for managing the complete system
- Agency web portal
- Workflow system
- Dissemination



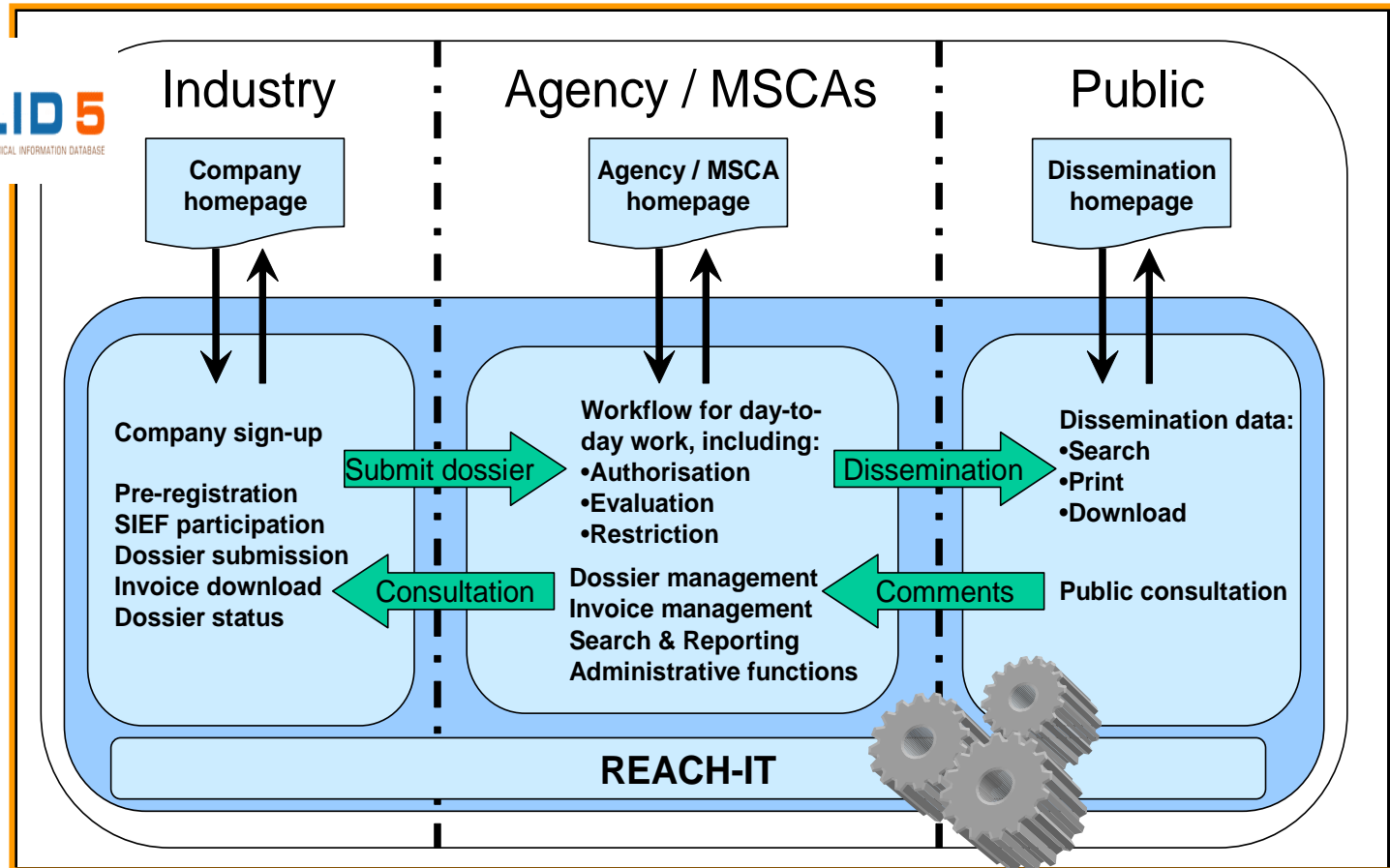
## IUCLID 5:

- Industry: tool for capturing data on chemicals, preparing and submitting dossiers
- Agency and MS: central data repository for all dossiers submitted and tool for preparing dossiers



# Three pillars of REACH-IT

## View of Users



Quelle: ECHA Stand: 08.05.2008





## Industry

- **Submission of dossiers prepared in IUCLID 5 for registration**
- **Submission reports sent back to registrants**
- **Notification systems (e.g. deadlines reminders)**
- **Status of dossiers**
- **Consultation of information (e.g. guidelines)**



## Industry

- from the 1th of June 2008 until 31th November 2008
- more than 65.000 companies have signed up REACH-IT
- more than 2.6000.000 pre-registrations have submitted to REACH-IT

# REACH Implementation Plan RIP 2.1 REACH-IT



## REACH Regulation, Article 111

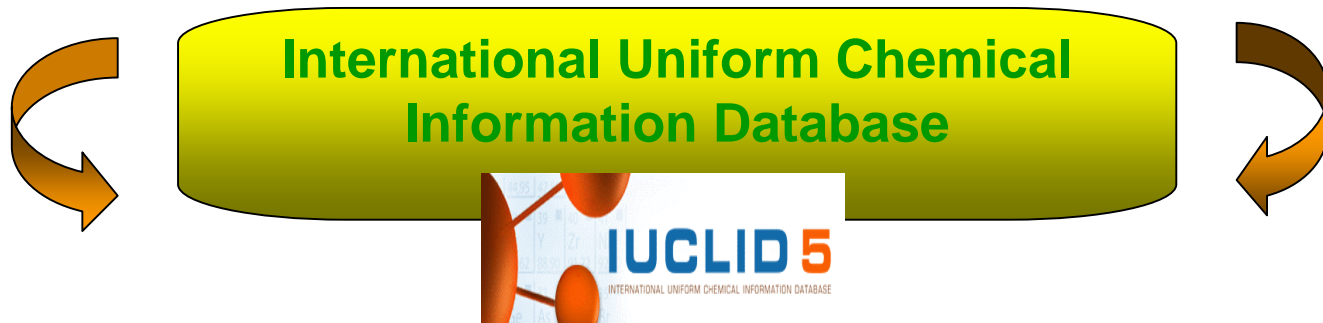
„Formats and software for submission of information to the  
European Chemical Agency“

*[..] the format for submission of the  
technical dossier [...] shall be  
**IUCLID 5***

# Key-Software IUCLID 5 XML-Interface



Key for harmonising and exchanging file between  
Industry, ECHA and Member States



Imperative for Integration and Exchange between  
IUCLID 5 and REACH-IT data base

# Homepage of IUCLID 5



**Tasks**

- Legal entity**: Create and update company /organisation related information. [New](#), [Update](#)
- Substance**: Create and update substance related information. [New](#), [Update](#)
- Template**: Create and update template related information. [New](#), [Update](#)
- Dossier**: View dossier data. [View](#), [Compare](#)
- Legal entity site**: Create and update legal entity sites. [New](#), [Update](#)
- Mixture**: Create and update mixture related information. [New](#), [Update](#)
- Category**: Create and update category related information. [New](#), [Update](#)

**Inventories**

- Inventory**: View EC inventory related information. [View](#), [Import](#)
- Reference substance**: Create and update reference substance related information. [New](#), [Update](#)
- Literature reference**: View literature reference inventory related information. [View](#)

**Tools and administration**

- Manage users, roles, preferences, etc.**: [User preferences](#), [Set password](#), [User management](#), [Role management](#)
- Import**: Import data from other IUCLID 5 systems. [Import](#), [Bulk import](#)

**Plugins**

- Migrate data**: Migrate data from IUCLID 4 to IUCLID 5 format. [Run](#)

- Tasks
- Inventories
- Tools and administration  
e.g. Import via XML-Interface
- Plugins e.g.  
Pre-registration  
Query-Tool  
Migration I4→I5 ....

# IUCLID 5 Data content



## Chapter 1 – General Information

- 1.1 Identification (Substance, L
- 1.2 Composition
- 1.3 Identifiers
- 1.4 Analytical information
- 1.5 Joint Submission
- 1.6 Sponsors
- 1.7 Suppliers
- 1.8 Recipients
- 1.9 PPORD

## Chapter 2 – C&L

- 2.1 GHS
- 2.2 EEC

## Chapter 3 – Manufacture, Use a

- 3.1 Technological Process
- 3.2 Estimated Quantities
- 3.3. Sites
- 3.4 Form in the Supply Chain
- 3.5 Identified uses and Exp. Sc
- 3.6 Uses advised against
- 3.7 Waste from Production and
- 3.8 Exposure estimates
- 3.9 Biocidal information
- 3.10 Application for Authorisati

## Chapter 4 - Physical & Chemical Properties

- 4.1 Appearance / Physical state
- 4.2 Melting Point
- .....
- .....

## Chapter 5 - Environmental fate and pathways

- 5.1 Stability
- 5.2 Biodegradation
- 5.3 Bioaccumulation
- 5.4 Transport and distribut
- 5.5 Environmental data
- 5.6 Additional informat

## Chapter 6 - Ecotoxicolo

- 6.1 Aquatic toxicity
- 6.2 Acute toxicity
- 6.3 Terrestrial toxicity
- 6.4 .....

## Chapter 7 - Toxicologic

- 7.1 Toxicokinetics, met
- 7.2 Acute toxicity
- 7.3 Irritation / corrosio
- 7.4 ....

## Chapter 8 - Analytical Methods

## Chapter 9 - Residues in food and feedingstuffs

- 9.1 Preliminary: Metabolism in livestock and crops
- 9.2 Preliminary: Residues in livestock and crops
- 9.3 .....

## Chapter 10 - Effectiveness against target organism

## Chapter 11 – Guidance on safe use

## Chapter 12 – Literature search

## Chapter 13 – Assessment Reports

# Enhancements of IUCLID 5



## Concept of Plugins

- ✓ Migration tool IUCLID 4→IUCLID 5, (New Chemicals)
- ✓ Pre-Registration
- ✓ Extended Querytool

Reportingtool: First version in March 2009 (?)

Tools for configuration and generation of:

- **Exposure scenarios (ES)**
- **Chemical Safety Assessment (CSA)**
- **Chemical Safety Reports (CSR)**

**Planning: September 2009**

# Discover of IUCLID 5-Data Query Tools



- ✓ **I 5 - Standard queries:**  
Basic functionalities
- ✓ **I 5 - Flexible queries:**  
Search of more than  
3000 items incl.  
Endpoint fact data
- o Queries via REACH-IT-  
Portal in the IUCLID 5 –  
database → Mid of  
2009

The screenshot shows the IUCLID 5 software interface. The window title is "beta test substance / beta test reference substance / Methanal / Methanal / 50-00-0 / Umweltbundesamt / Dessau / Germany / IUCLID 5". The interface is divided into several panes. On the left is a "Navigation" pane with a tree view showing various data sections such as "1.2 Composition", "1.3 Identifiers", "1.4 Analytical information", "1.5 Joint submission", "1.6 Sponsors", "1.7 Suppliers", "1.8 Recipients", "1.9 Product and process oriented research and development", "2 Classification and Labelling", "3 Manufacture, use and exposure", "4 Physical and chemical properties", "4.1 Appearance/physical state/colour", "4.2 Melting point/freezing point", "4.3 Boiling point", "4.7 Partition coefficient", "4.8 Water solubility", "4.9 Solubility in organic solvents / fat solubility", "4.10 Surface tension", "4.11 Flash point", "4.12 Auto flammability", "4.13 Flammability", "4.14 Explosiveness", "4.15 Oxidizing properties", "4.16 Oxidation reduction potential", "4.17 Stability in organic solvents and identity of relevant deg.", "4.18 Storage stability and reactivity towards container materi.", "4.19 Stability: thermal, sunlight, metals", "4.20 pH", "4.21 Dissociation constant", "4.22 Viscosity", "4.23 Additional physico-chemical information", "5 Environmental fate and pathways", "5.1 Stability", "5.1.1 Phototransformation in air", "5.1.2 Hydrolysis", "5.1.3 Phototransformation in water", "5.1.4 Phototransformation in soil", "5.2 Biodegradation". The main content area on the right displays "Endpoint study record: Melting point/freezing point.001". It includes a "Results and discussions" section with a table for "Melting / freezing point" showing values for "Melt./freez. pt.", "Atm. pressure", "Decomposition", "Decomp. temp.", "Sublimation", and "Subst. temp.". The table shows a value of "ca. +117 °C" for "Melt./freez. pt." and ">1023 -- <= 1024 bar" for "Atm. pressure". Below the table are buttons for "Add...", "Edit...", and "Delete", along with "Move up" and "Move down" arrows. The "Information" pane at the bottom shows "Type: Endpoint study record", "UIUCS: IUCS-0f41179b-1aaf-45f6-9a4a-93df10787a3c", and "Dossier UIUCS: 0". It also has checkboxes for "Selected", "Copy protected", and "Subset of original".



# Concept for confidential data

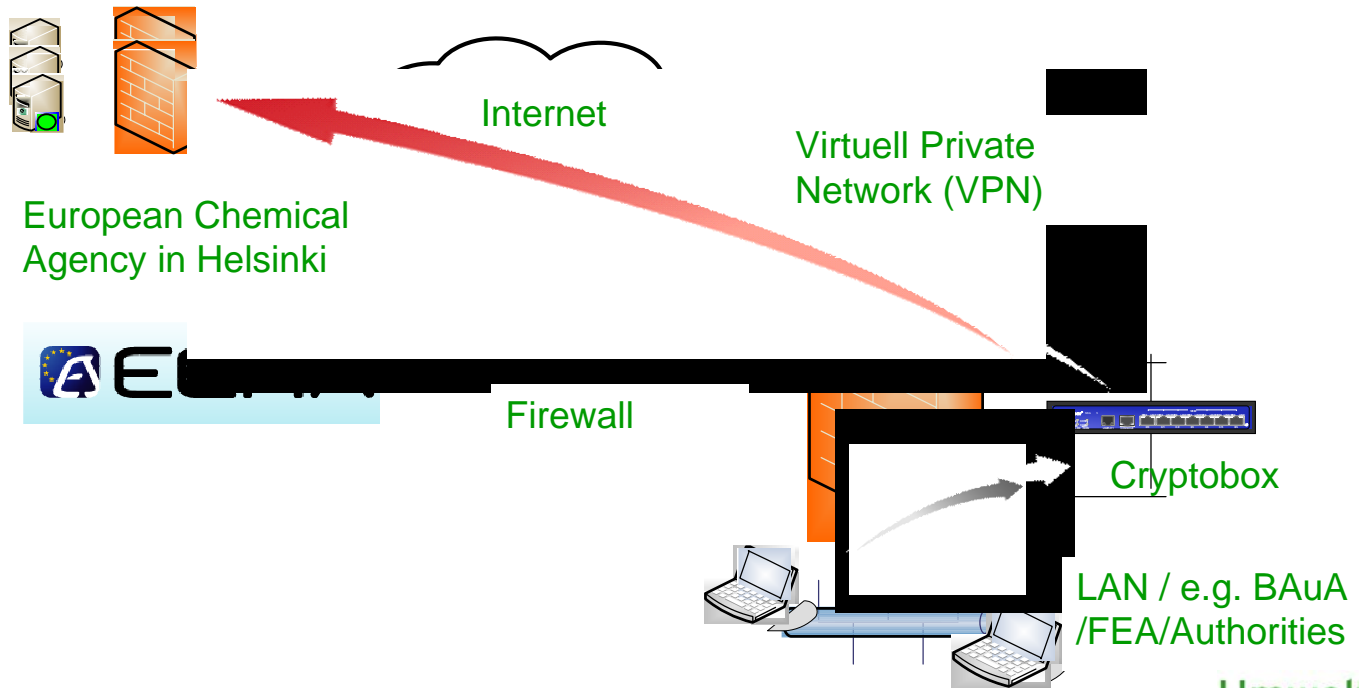


## Security Officer Network Group

According to the Directive:

- ECHA and the Member States are responsible for the security of the data
  - Security Guidelines for Datamanagement
  - Secure Technical Infrastructure

# Network Topology of the IT-Infrastructure

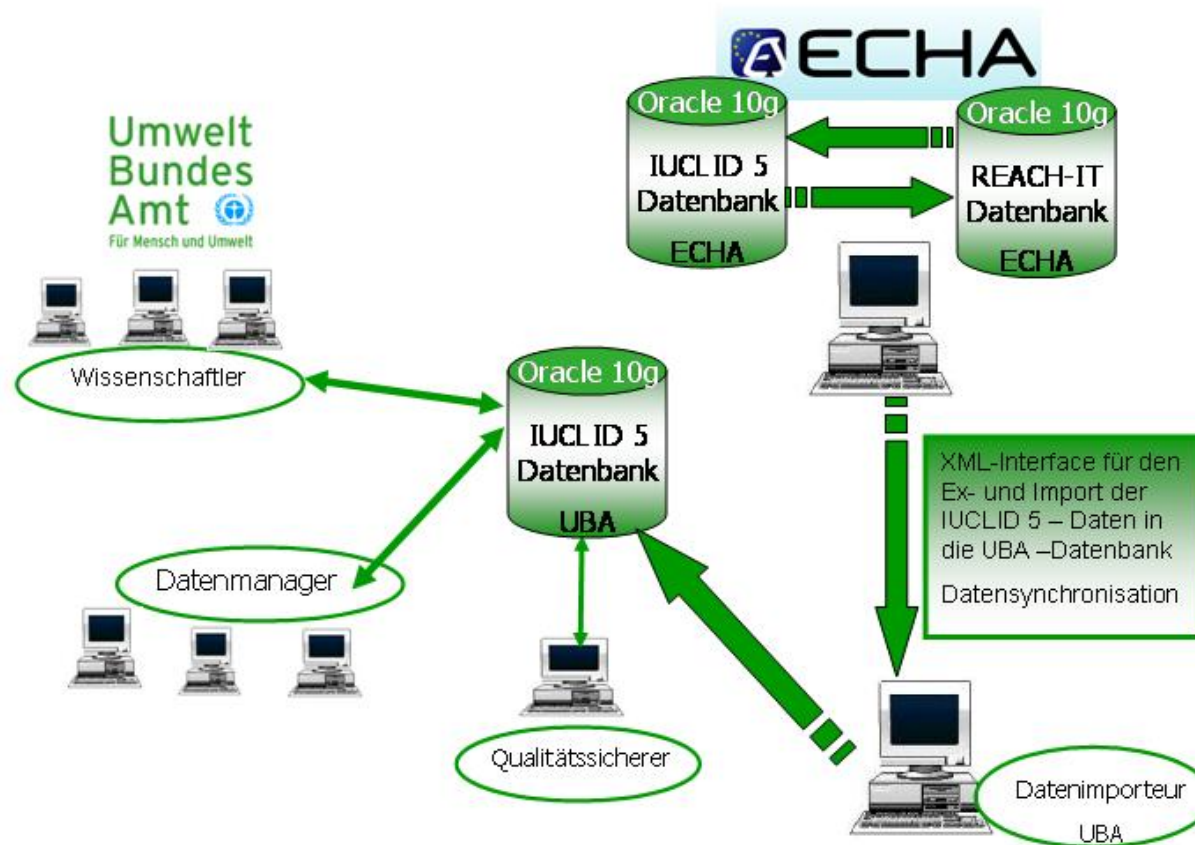


LAN: Local Area Network

Cryptobox: Encoding of the requests

Firewall: Software and Hardware components in the Authorities/Agencies  
e.g..Router

# Dataflow from ECHA to FEA





- W3C-Standard and Open-Source Software
- XML - Interface key for standard data exchange via REACH-IT and IUCLID 5
- high scalability, platform and system independence, simple data exchange



- Highly acceptance by many national and international authorities
- Use of IUCLID 5 for non-REACH jurisdictions is therefore explicitly endorsed
- In 2009 Web Services, enabling IUCLID 5 to directly communicate with other software applications

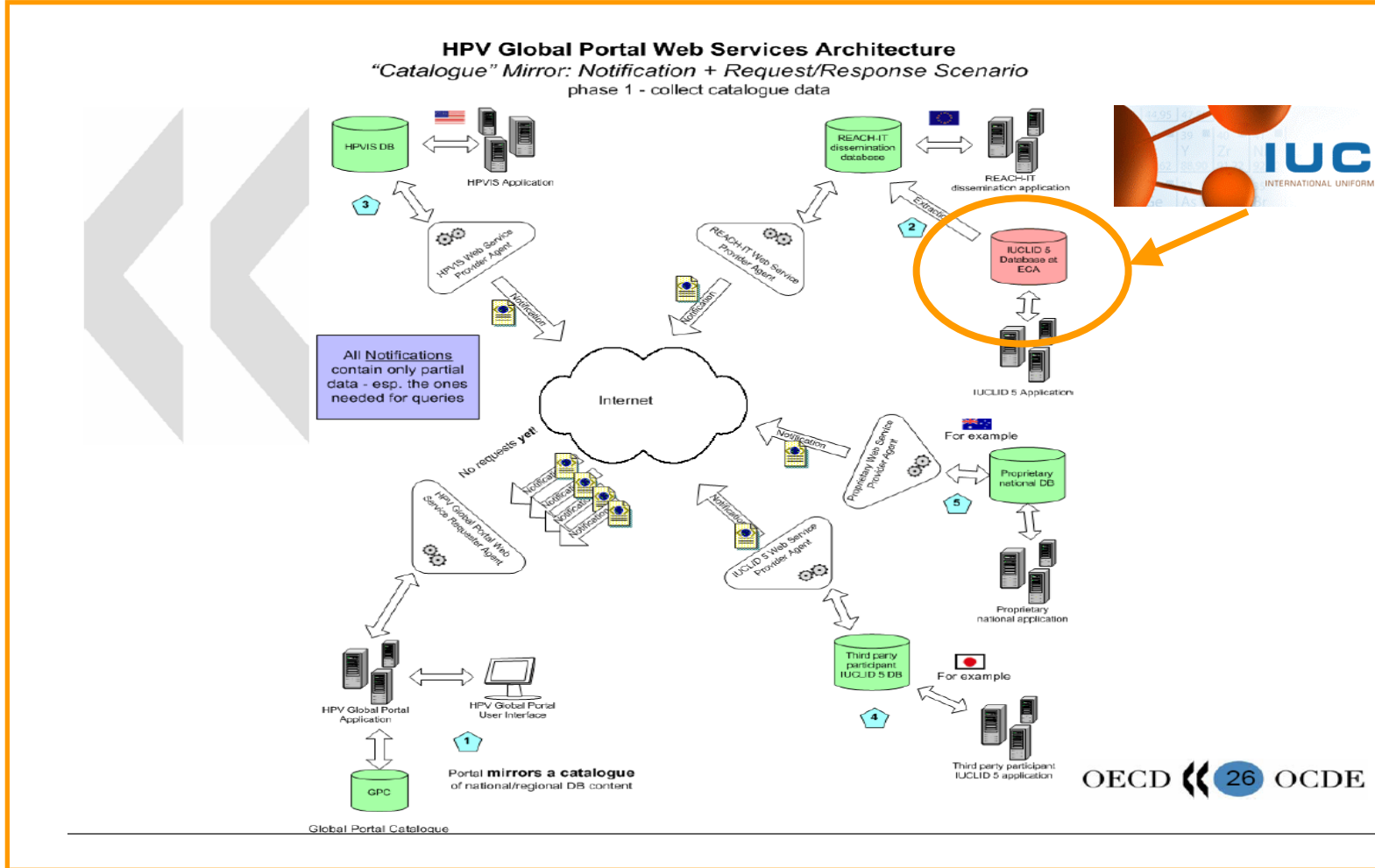
# Use for other legislations of chemicals



- High Production Value chemicals
- EU Biocides
  - Active substance
  - Product (preparation)
- In discussion:
  - EU Pesticides

# HPV Global Portal OECD

<http://webnet3.oecd.org/echemportal/>



# Lesson Learned for SEIS



- Create a methodology for the data concept with robust standards for the data format
- Underlay it with a legislation
- Use XML – interfaces for data exchange
- Define processes and roles for the data flow and data management
- Use a workflow management system to underpin these processes
- Install procedures for the bi-directional data flows



Benefit for all parties







We reach it !!!  
**We reach it !!!**

**More information you will find:**

**[http://echa.europa.eu/news/events\\_en.asp](http://echa.europa.eu/news/events_en.asp)**  
[http://echa.europa.eu/news/events\\_en.asp](http://echa.europa.eu/news/events_en.asp)