



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.

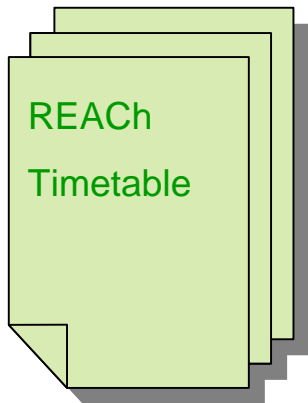




- Risk assessment for human health and the environment (exposure scenarios)
- Conducting Chemical Safety Assessment (CSA)
- Preparing detailed Chemical Safety Report (CSR)

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

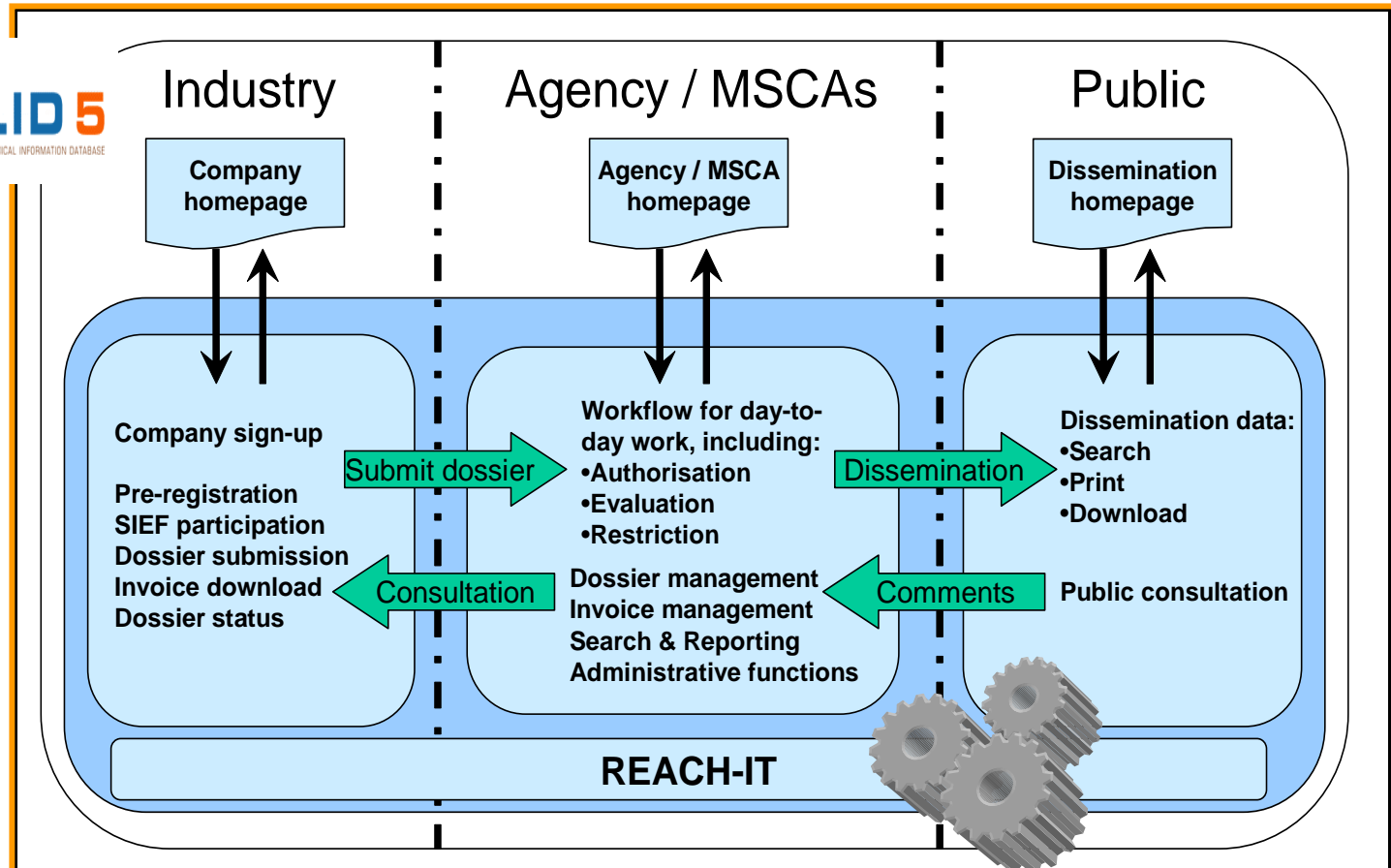


Three pillars of REACH-IT

View of Users



IUCLID 5
INTERNATIONAL UNIFORM CHEMICAL INFORMATION DATABASE



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

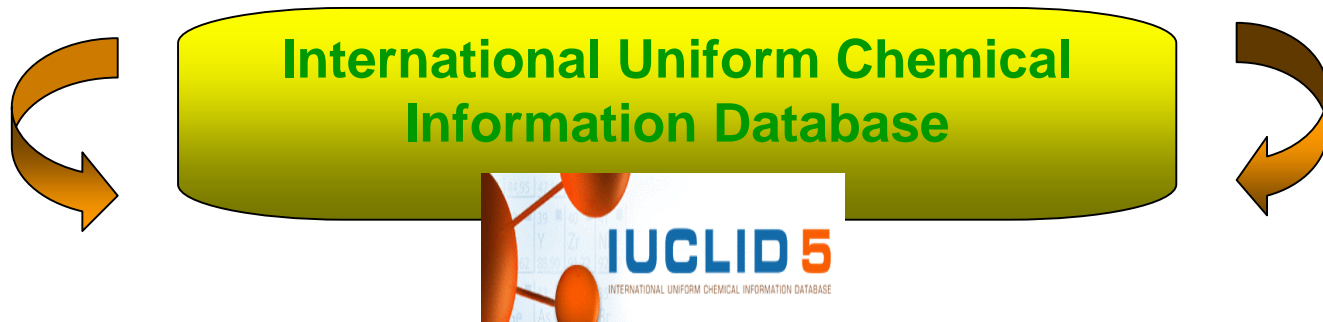
„Formats and software for submission of information to the
European Chemical Agency“

*[..] 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

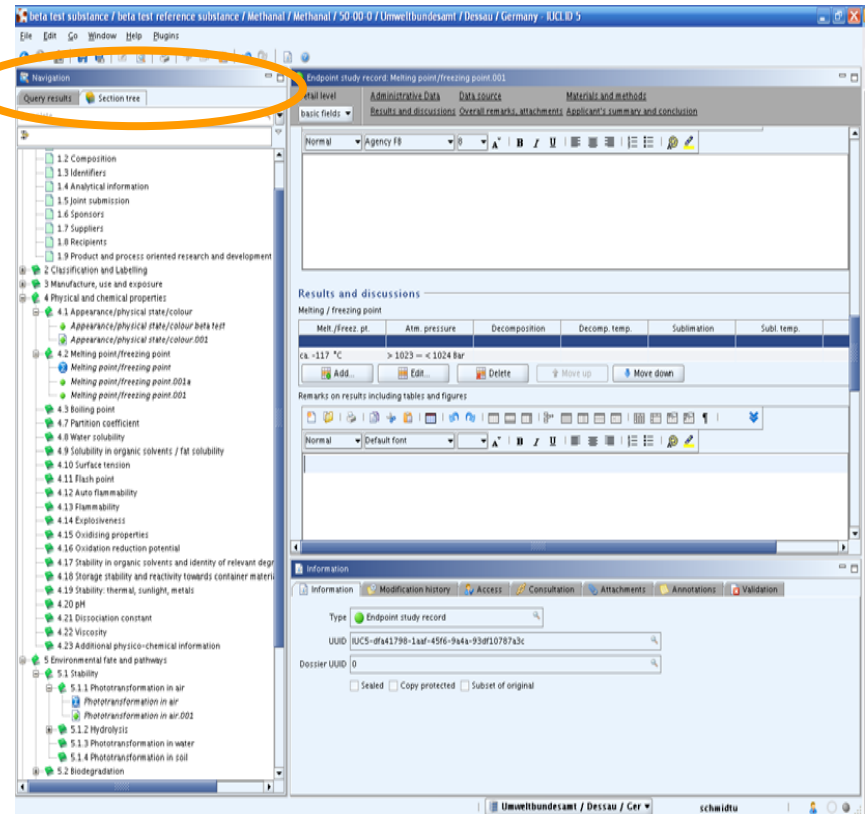
Discover of IUCLID 5-Data Query Tools



✓ **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 displays the IUCLID 5 software interface. The left pane shows a hierarchical tree of data sections, with 'Melting point/freezing point' selected. The right pane shows the 'Endpoint study record' for this property, including a table of values for different conditions. An orange circle highlights the 'Query results' and 'Section tree' tabs in the navigation bar.

Melt./freez. pt.	Atm. pressure	Decomposition	Decomp. temp.	Sublimation	Subst. temp.
ca. +117 °C	>1023	=<1024 bar			

Concept for confidential data

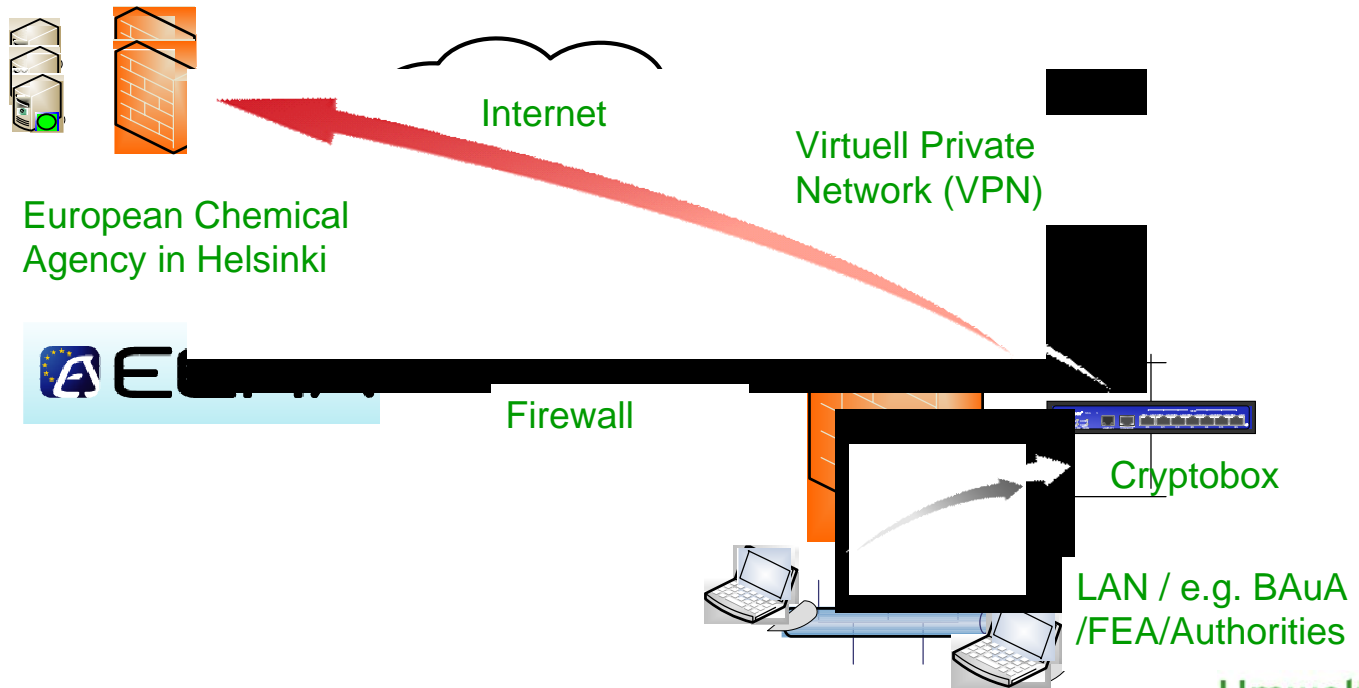


Security Officer Network Group

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

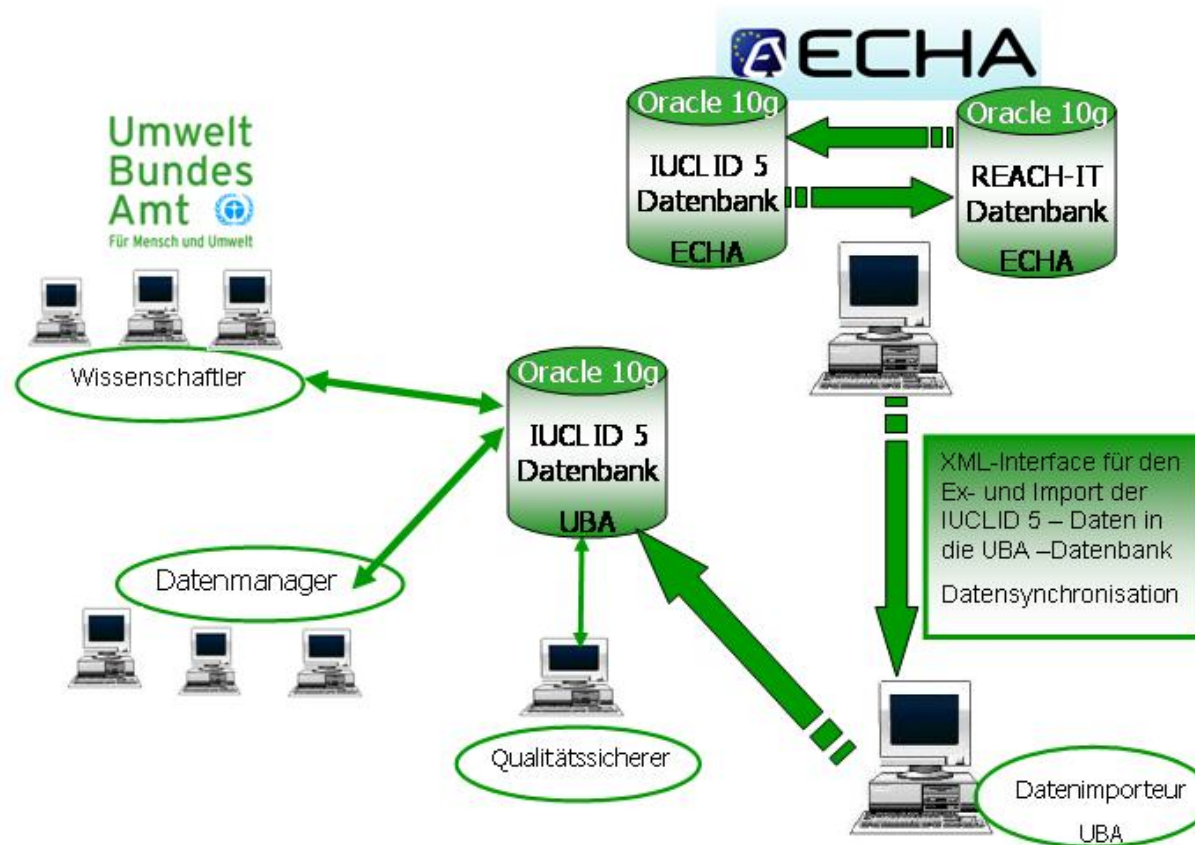


LAN: Local Area Network

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

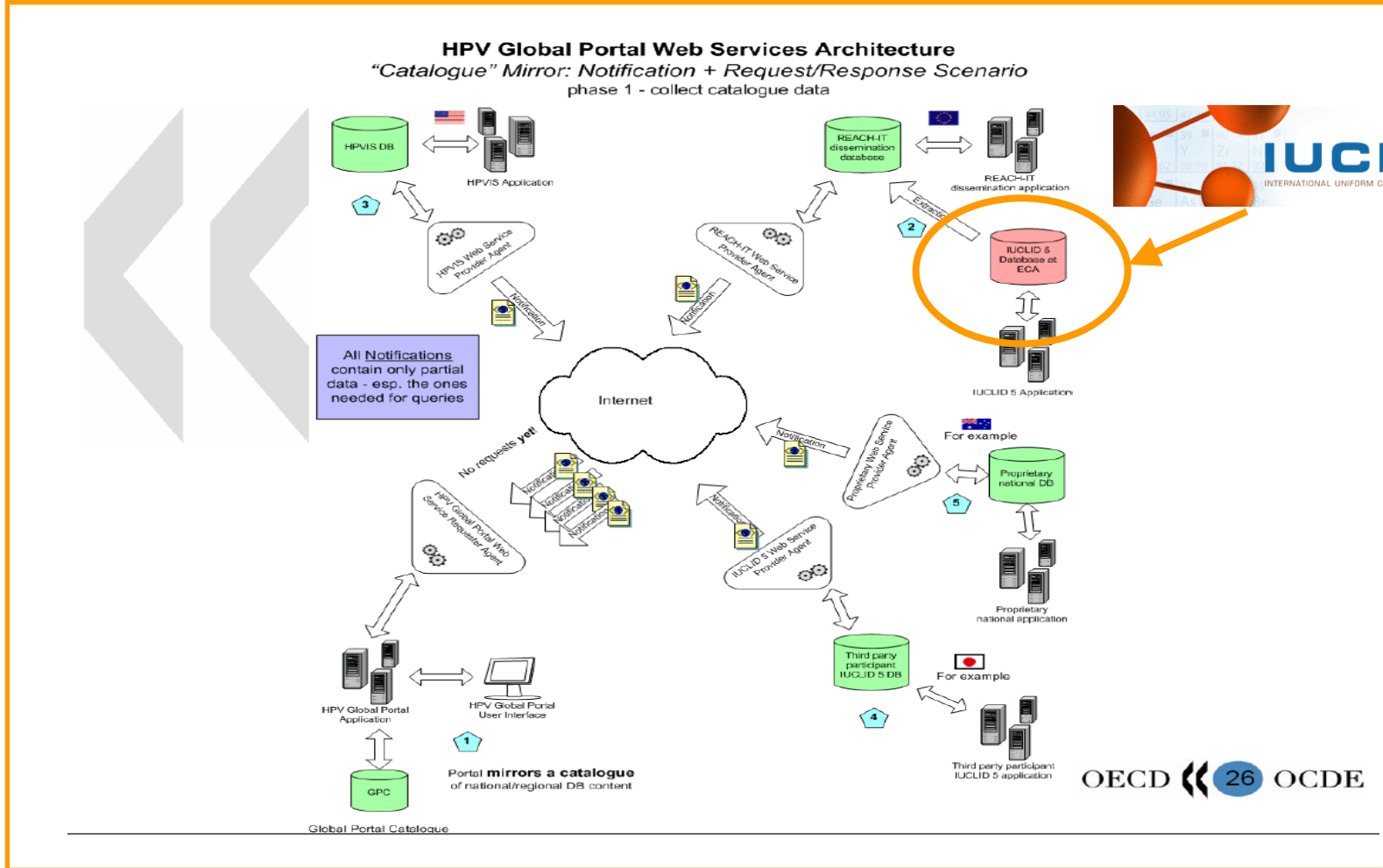
Use for other legislations of chemicals



- 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