



Umwelt Bundes Amt  **REACH** 

Workflows and Software Tools for the Process of Registration, Evaluation, Authorisation and Restriction of European Chemicals

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Unit IV2.1- Information Systems on Chemical Safety

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Umwelt Bundes Amt  **Agenda** 

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

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Registration, Evaluation, Authorisation
and restriction of Chemicals 

REACH Regulation 2006/1907/EC

The legislation should ensure a high level of protection of human health and the environment from the risk by chemical substances. Manufacturers and importers of substances in quantities of 1 tonne or more shall submit a registration to the European Chemical Agency (ECHA) in Helsinki.

→ finally adopted by EU Member States in December 2006

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Umwelt Bundes Amt  **REACH**
Registration, Evaluation, Authorisation
and restriction of Chemicals 


REACH Information Sharing

Manufacturers and importers are encouraged to collaborate to the preparation of registration dossiers, by

- sharing information on hazard and exposure for the chemical substances
- formation of voluntary consortia to facilitate the information sharing.

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Umwelt Bundes Amt  **Concept of REACH** 

 **Greater Responsibility on Industry**



→ Risk assessment for humans and the environment (exposure scenarios)


→ Conducting Chemical Safety Assessment (CSA)

→ Preparing detailed Chemical Safety Report (CSR)

No data – no market!



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Umwelt Bundes Amt  **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 ends
- **1 January 2009** ECHA publishes list of pre-registered substances and commences listing substances potentially requiring authorisation
- **1 December 2010** Registration deadline for phase-in substances manufactured or imported 1,000 tonnes + per annum

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Umwelt Bundes Amt  **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 for any submissions to the Agency. Member States, manufactures, importers, distributors or downstream users **shall use these formats** [...] in their submissions to the Agency pursuant to this Regulation. [...] For the purposes of registration, 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**."*




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Umwelt Bundes Amt  **What does it means ?** 
REACH Implementation Plan – RIP 2.1 REACH-IT

Objectives of REACH-IT:

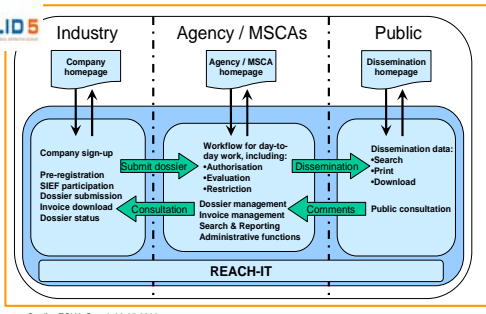
- **Development of an IT-system that enables the ECHA to receive and store pre-registration and inquiry dossiers, registrations, notifications, reports and payments**
- **Simply and protected retrieval to the information via REACH-Portal WebSide by the Industry, Agency and MSCAs**
- **Dissemination of non-confidential registration dossier data and other relevant data for the public**

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Three pillars of REACH-IT

View of Users



Quelle: ECHA Stand: 08.05.2008

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Two Main IT-Systems

REACH-IT:


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

IUCLID 5:

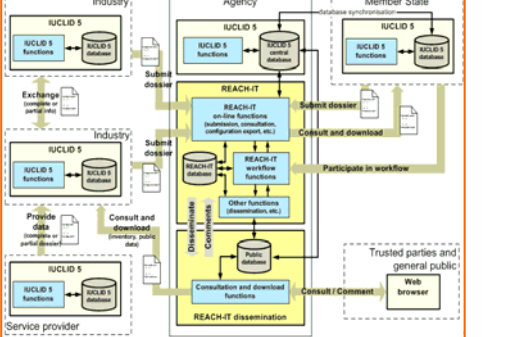
- Industry: tool for capturing data on chemicals, preparing and submitting dossiers
- Agency and MS: central data repository for all dossiers submitted and tool for preparing dossiers

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Workflows and Interaction



Quelle: ECHA 2008

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REACH-IT-Workflows: Functionalities for Industry

Industry

- Data sharing: Pre-registration, SIEF, inquiry process
- Submission of dossiers prepared in IUCLID 5 (e.g. registration)
- Online encoding and submission of dossiers with limited data requirements
- Follow-up functionalities
 - submission reports sent back to registrants
 - notification systems (e.g. deadlines reminders)
 - status of dossiers (i.e. a company can consult REACH-IT for tracking its own dossiers)
- Consultation of information (e.g. guidelines)

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REACH-IT-Workflows: Functionalities for Authorities

ECHA/Agency and Member States (MS)

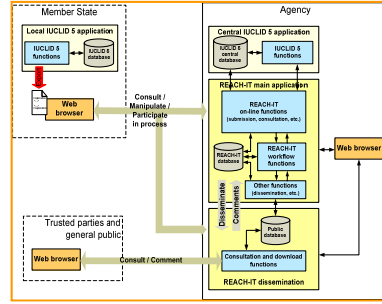
- Workflow system accessed by Agency staff and MS staff (notification system by email, dashboards,...)
- Follow-up of dossiers and updates
- Follow-up of Committee work, decisions, opinions, etc.
- Dissemination of information
- Third parties consultation

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REACH-IT: How it will work?

→ Support for Agency (ECHA) and MS work on evaluation, authorisation and restriction



→ Objectives of REACH

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REACH-IT-Workflows: Functionalities for the public

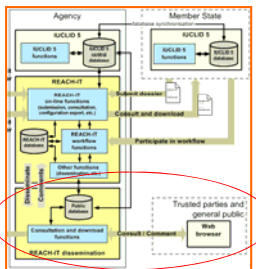
General Public and trusted parties

According to the regulation of REACH Art. 117 (1) and 119:


The Agency and Member States should allow electronic public access to information in accordance with Directive 2003/4/EC...

...selected non-confidential data of the registration dossier shall be published

...Retrieval and requests via the „Dissemination Website“ of REACH-IT



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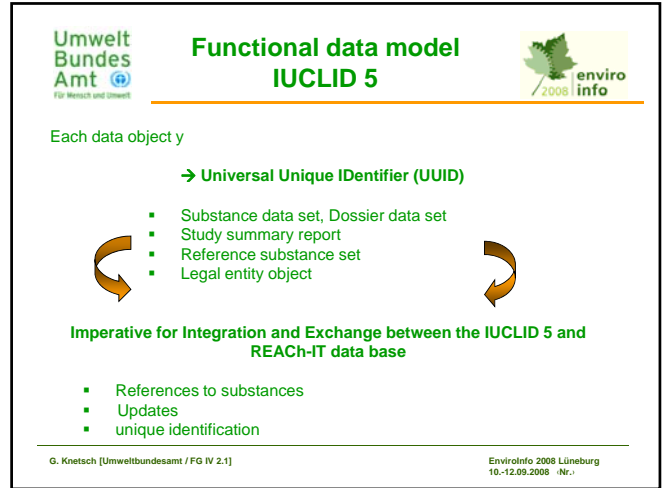
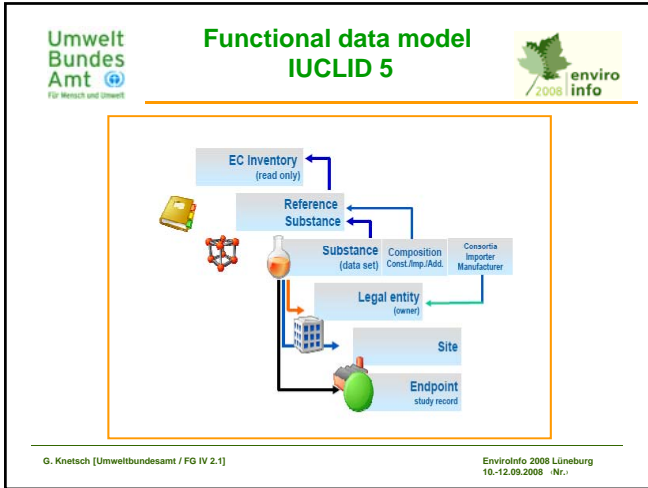
Software Application IUCLID 5

- ...it implements the 86 Harmonised Templates developed by the OECD (Organisation for Economic Cooperation and Development)
- ... it allows to enter, manage, store and exchange information on intrinsic and hazard properties of chemical substances
- ...it allows to prepare and submit dossiers in XML-standard format
- ... it's compatible with chemical legislation and programme requirements in different part of the world, inter alia the EU Biocides Directive and the OECD High Production Volume (HPV) Programme

International Uniform Chemical Information Database

IUCLID

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IUCLID 5 Data content

Chapter 1 - General Information 1.1 Identification (Substance, I 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 PPFORD Chapter 2 - C&L 2.1 GHS 2.2 EEC Chapter 3 - Manufacture, Use 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 Authorizat	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 distribu 5.5 Environmental data 5.6 Additional informat Chapter 6 - Ecotoxicity 6.1 Aquatic toxicity 6.2 Acute toxicity 6.3 Terrestrial toxicity 6.4 Chapter 7 - Toxicology 7.1 Toxicokinetics, met 7.2 Acute toxicity 7.3 Irritation / corrosio 7.4	Chapter 8 - Analytical Methods Chapter 9 - Residues in food and feedings 9.1 Preliminary: Metabolism in livestock and crop 9.2 Preliminary: Residues in livestock and crops 9.3 Chapter 10 - Effectiveness against target organis Chapter 11 - Guidance on safe use Chapter 12 - Literature search Chapter 13 - Assessment Reports
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„Key“ - Software IUCLID 5

The screenshot shows the 'Starting page' of the IUCLID 5 software. It features a grid of icons representing different functions: 'Legal entity data', 'Substances', 'Endpoints', 'Assessment reports', 'Literature references', 'Management', 'Reports', and 'Plugins'. The interface is designed for easy navigation and access to various data and tools.

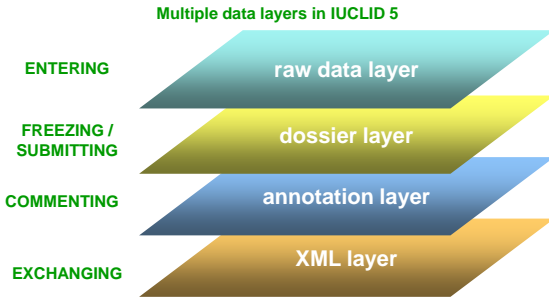
„Starting page“ of IUCLID 5:

- Tasks
- Inventories
- Tools and administration
- Import via XML-Interface
- Plugins for migration of IUCLID 4-Data into IUCLID 5 - format, Pre-registration

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Umwelt Bundes Amt  **IUCLID 5: abstraction layers**

Multiple data layers in IUCLID 5




ENTERING raw data layer

FREEZING / SUBMITTING dossier layer

COMMENTING annotation layer

EXCHANGING XML layer

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Umwelt Bundes Amt  **Technical architecture IUCLID 5**

Two technological concepts:

- Distributed Network Application with several Web-Clients
- Stand-alone Application

Data Base:

- RDBMS ORCALE 10.2 (commercial data base system)
- PostgreSQL (open source-product)


Servlet Engine:

- BEA Web Logic
- Apache Tomcat

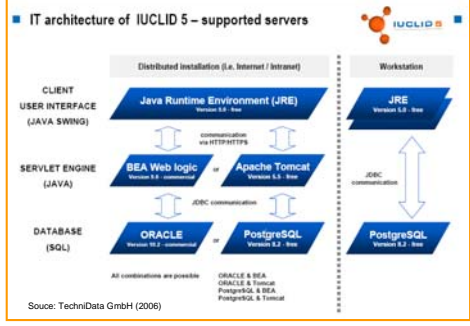
FrontEnd:

- Client User Interface (Java Swing)
- Java Runtime Environment
- Access via Webbrowser (Internet Explorer, Firefox)

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Umwelt Bundes Amt  **Technical Architecture of IUCLID 5**

IT architecture of IUCLID 5 – supported servers



Source: TechniData GmbH (2006)

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Umwelt Bundes Amt  **Enhancements of IUCLID 5**

Plugins for IUCLID 5

- ✓ Migration tool IUCLID 4→IUCLID 5, (New Chemicals)
- ✓ Pre-Registrierung
- o Search- and Reportingtool →Planning: October 2008
- o Tools for configuration and generation of:
 - oExposure scenarios (ES)
 - oChemical Safety Assessment (CSA)
 - oChemical Safety Reports (CSR)
 - Planning: September 2009

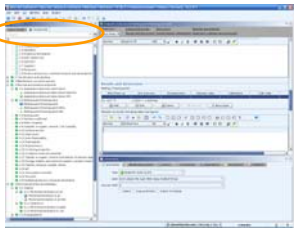
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Search-Plugin IUCLID 5

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- ✓ **15 Standardqueries:**
Basic functionalities
- **15 Flexiblequeries:**
Search of all available data incl. Endpoint fact data
- **REACH – IT-Queries:**
Basic functionalities for administrative data, number of pre-registration and dossiers data
- **Complex query module for research in REACH-ITund I 5:**
Meta-daten of the legal entity in combination with fact data e.g. substance properties

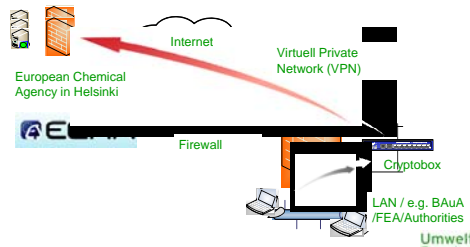


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Network Topology of the IT-Infrastructure

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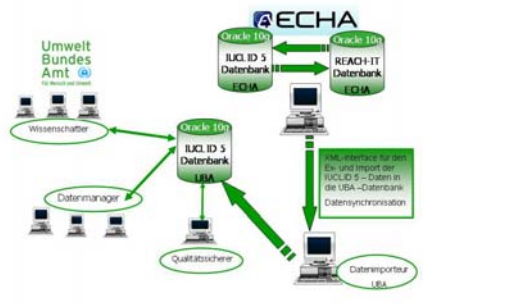
LAN: Local Area Network
Cryptobox: Encoding of the requests
Firewall: Software and Hardware components in the Authorities/Agencies e.g., Router

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Dataflow from ECHA to FEA

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Outlook - Perspectives

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- Complex IT System IUCLID 5 with a lot of functionalities can be used for a large number of purposes.
- Data storage formats implemented have been developed in co-operation with the Organisation for Economic Co-operation and Development (OECD)
- Highly acceptance by many national and international regulatory authorities.
- Use of IUCLID 5 for non-REACH jurisdictions is therefore explicitly endorsed.


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Outlook - Perspectives

- The fact that data in IUCLID 5 can be used for other purposes than REACH may offset some of the data collection costs.
- UCLID 5 data model also features Biocides/Pesticides elements and data collected under REACH can thus be re-used once complemented with data on biocidal or pesticidal properties - for data reporting obligations under other legislation.

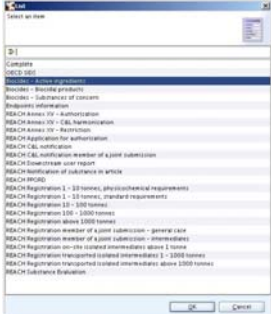
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Use for other legislations of chemicals

Dossiers can be created for:

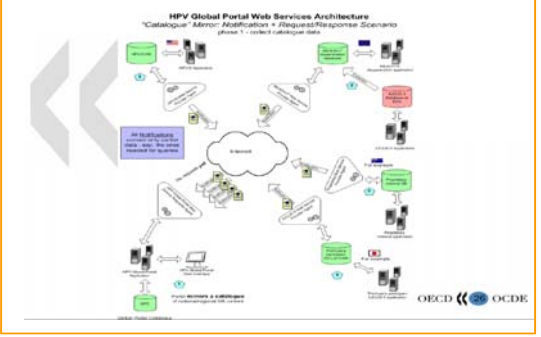
- OECD High Production Value chemicals
- EU Biocides
 - Active substance
 - Product (preparation)
- In discussion:
 - EU Pesticides




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HPV Global Portal WebService





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Outlook IUCLID 6 ?

I5/I6 could be a solution for efficient data collection and exchange of information between parties

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We reach it !!!

More information you will find:

http://echa.europa.eu/news/events_en.asp