



Bayer

REACH Workshop
**IUCLID 5 and Chemical Safety
Report**

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Bonn

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Environment & Sustainability**

IUCLID/ REACH IT

REACH IT is a RIP Project – **RIP 2**

But: Talking about REACH IT means two systems:

1. **IUCLID 5** – database
2. **REACH IT** – Central IT system of the future European Chemicals Agency

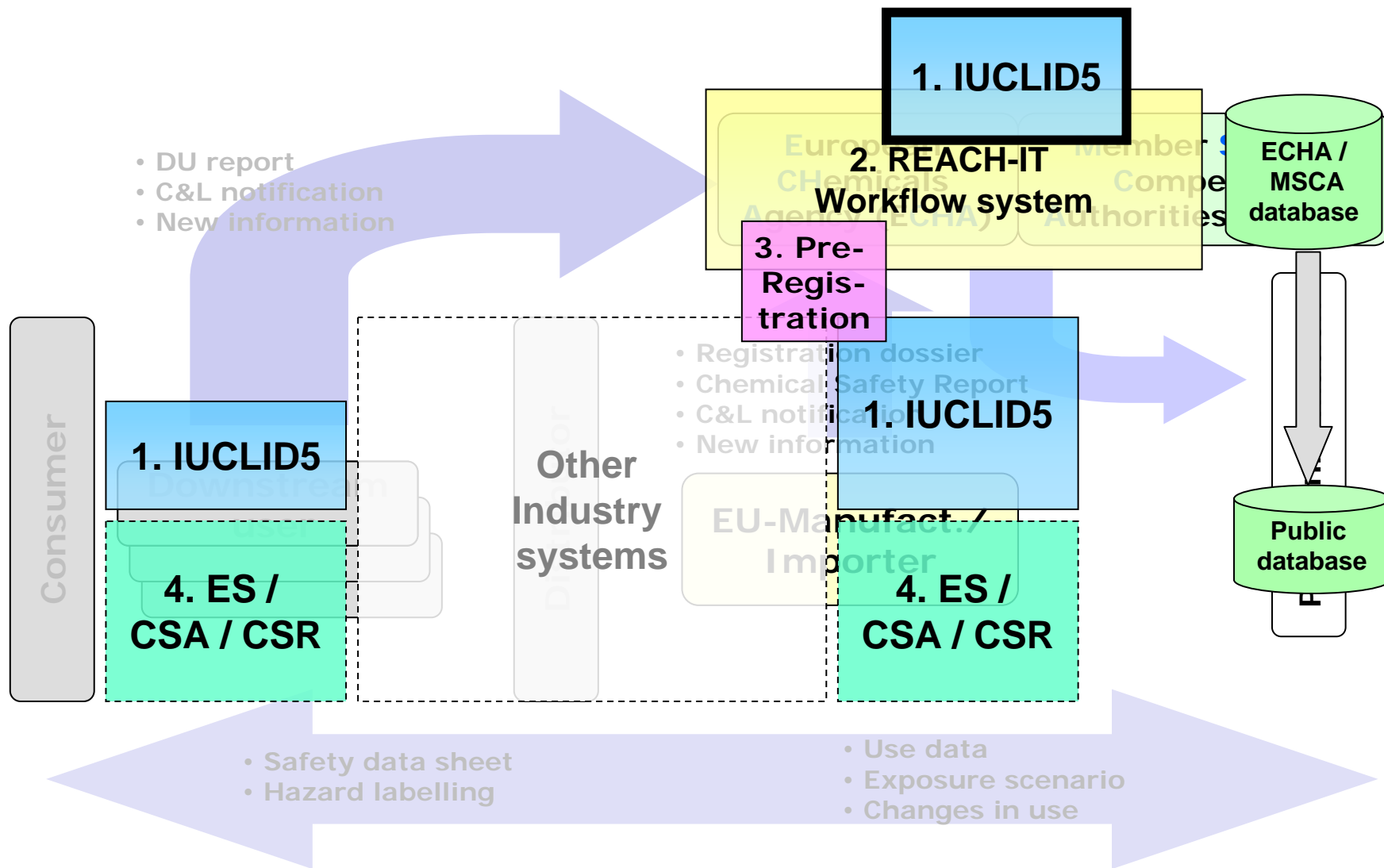
IUCLID5

- ❖ In **Industry**:
 - The tool for capturing data on chemicals, preparing and submitting dossiers
- ❖ In the **Agency & in Member states competent authorities**:
 - The **central data repository** for all dossiers submitted
 - The basis for **dossier compliance check** and **substance evaluation**
 - The basis for **priority setting**, data mining,...
- ❖ **Accessed centrally** by the Agency & the Member states competent authorities personnel

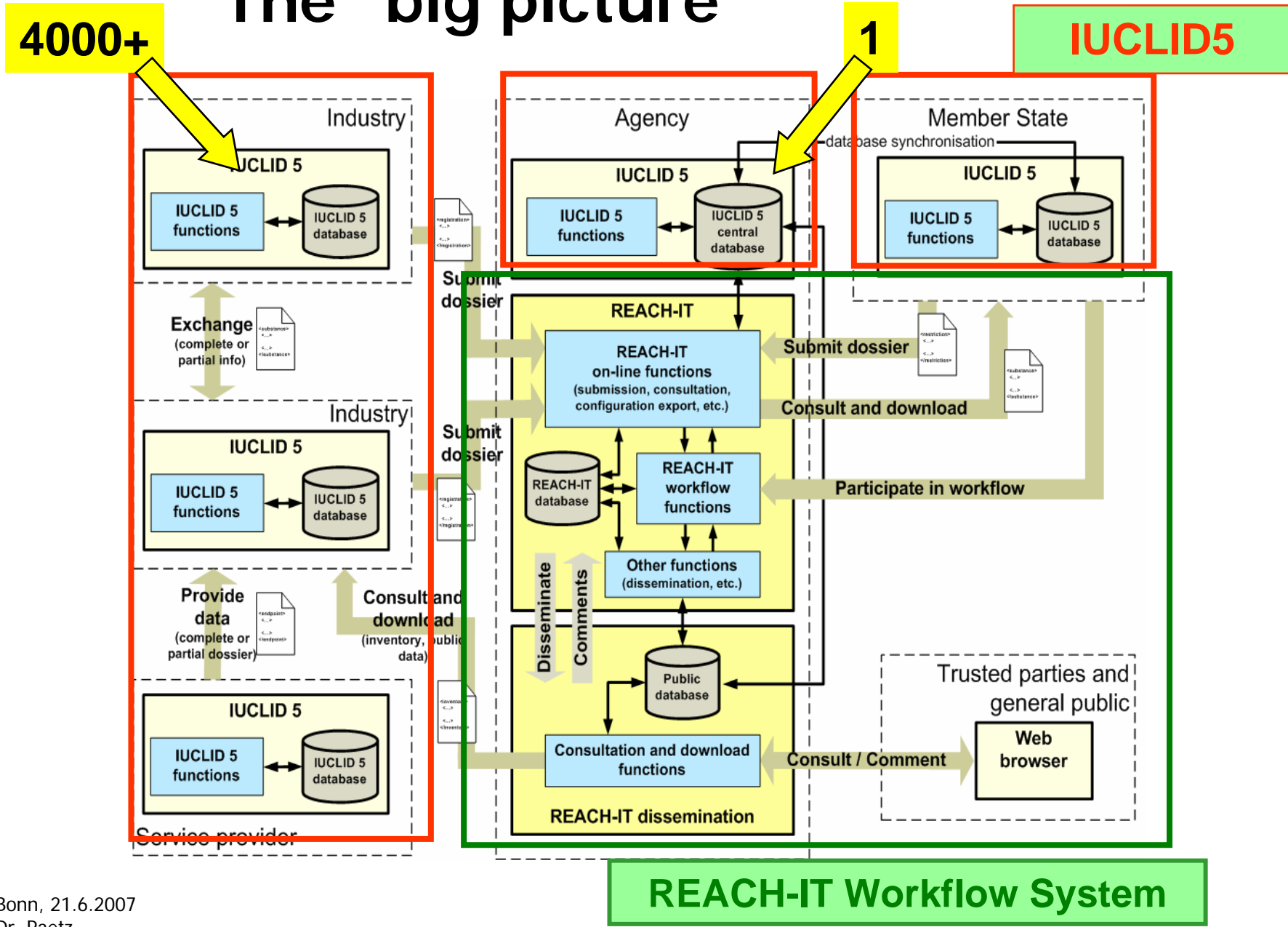
REACH-IT WF system

- ❖ **Central IT system** of the future European Chemicals Agency that will support the implementation of the REACH legislation
- ❖ It includes:
 - A **web portal** for submission and consultation of information by industry
 - A **workflow system** for full control of all tasks triggered by REACH
 - Central database of all information necessary to manage the system (**REACH-IT database**): identification and status of dossiers, decisions, ...
 - A **dissemination system** for publishing non-confidential data on the Agency website
 - **Integration mechanisms** with other Agency systems, in particular IUCLID 5, but also payment, reporting systems, e-mails...

IT systems developed by EU Commission

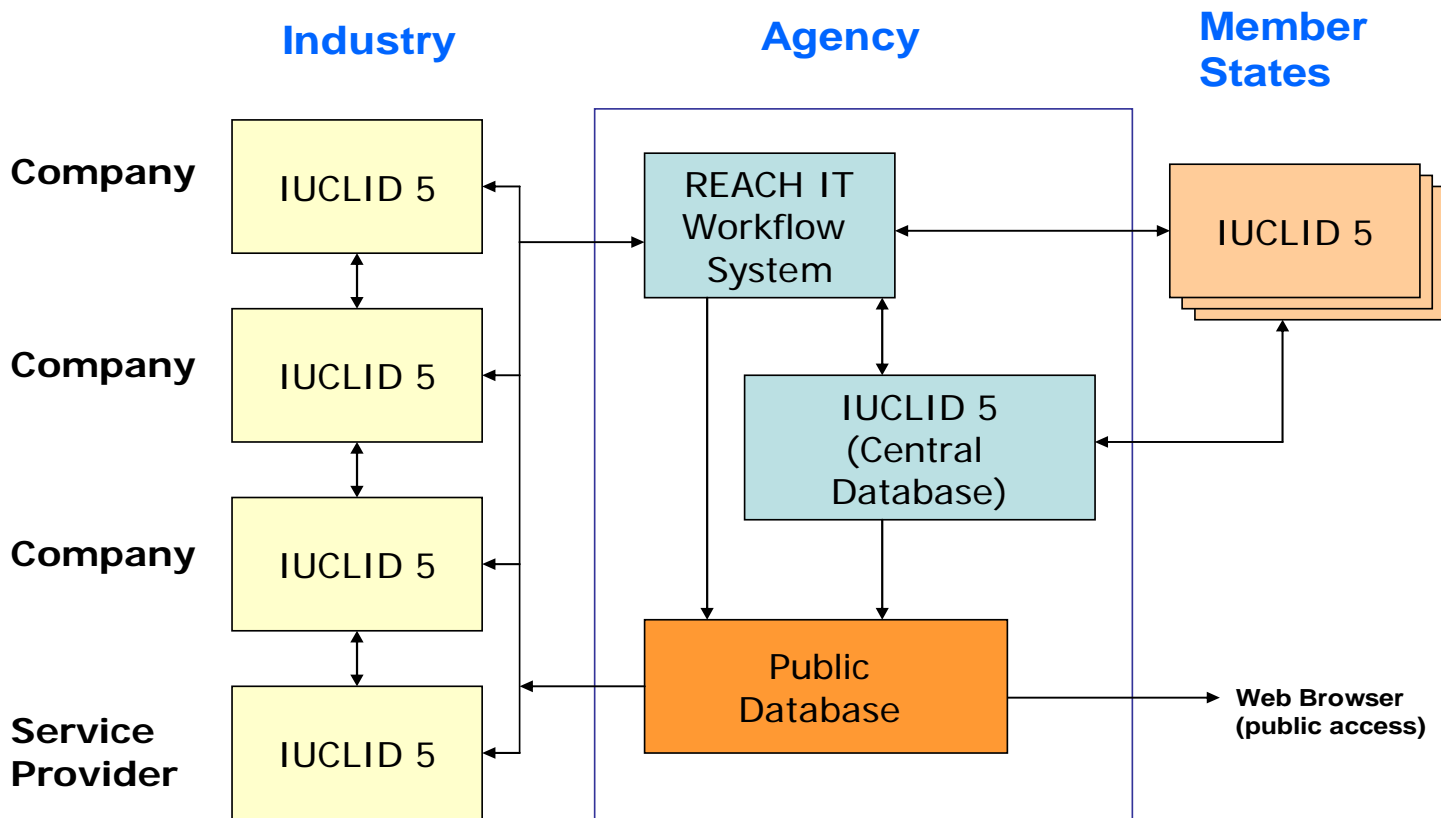


The "big picture"



REACH-IT Workflow System

IUCLID5 dataflow

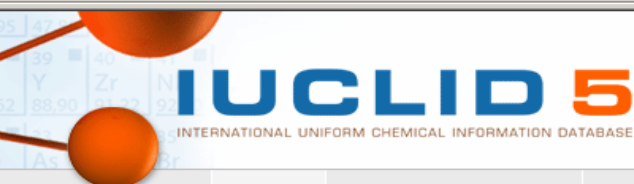


Basis of IUCLID

- ❖ IUCLID 5 is based on the [OECD Harmonized Templates](#).
- ❖ Developed by OECD, industry and authorities
- ❖ IUCLID is used in several programs and legislations (Biocide directive, Pesticide directive, OECD existing chemicals program, ICCA HPV Initiative, US EPA HPV Challenge Program **and for REACH**).
- ❖ Every endpoint (intrinsic properties) has [exact specified entry fields](#) (e.g. test type, method, species, number of animals, route, control group, result, value, free tests...)
- ❖ Templates are additionally available to facilitate the use of free text
- ❖ These data sets are the basis of IUCLID. They are implemented 1:1
- ❖ IUCLID gives several [views](#), this allows to see only special endpoints (e.g. Annex VII for substances between 1 und 10 t)
- ❖ But: always the [complete endpoint](#) (all fields)!

IUCLID5

- ❖ Rollout: June 12, 2007 (download from <http://iuclid.eu>)
- ❖ Will be made available to Industry **free of charge**
- ❖ Can be installed either **stand-alone** or in **network**
May run on top of:
 - **Open source software** (PostgreSQL, Tomcat)
or
 - **Commercial software** (Oracle, Bea Weblogic)
(logical choice for companies which already have Oracle / Bea installed)
- ❖ Companies need to analyse IUCLID5 system setup / configuration options **before starting**



Username: Password:
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English (en) ▾

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IUCLID 5 plays a central role in the IT environments of all organisations that have to cope with data submission requirements of REACH and other programmes (OECD HPV, EU Biocides and others). Industry stakeholders, EU Member States, the European Chemicals Agency (ECHA), and any other interested party obtain the IUCLID installation kit from this web site; once installed, the local IUCLIDs are the essential tool to capture & store, submit, and exchange data on chemical substances stored according the format of the OECD [[Harmonised Templates](#)]

News

[\[12.06.2007\] IUCLID 5 is now available!](#)

Both the stand-alone version and the distributed version of IUCLID 5 can be downloaded in the "Get IUCLID 5" section.

[\[01.06.2007\] Opening of the European Chemicals Agency](#)

Opening of the European Chemicals Agency

[\[01.06.2007\] IUCLID 5 coming soon!](#)

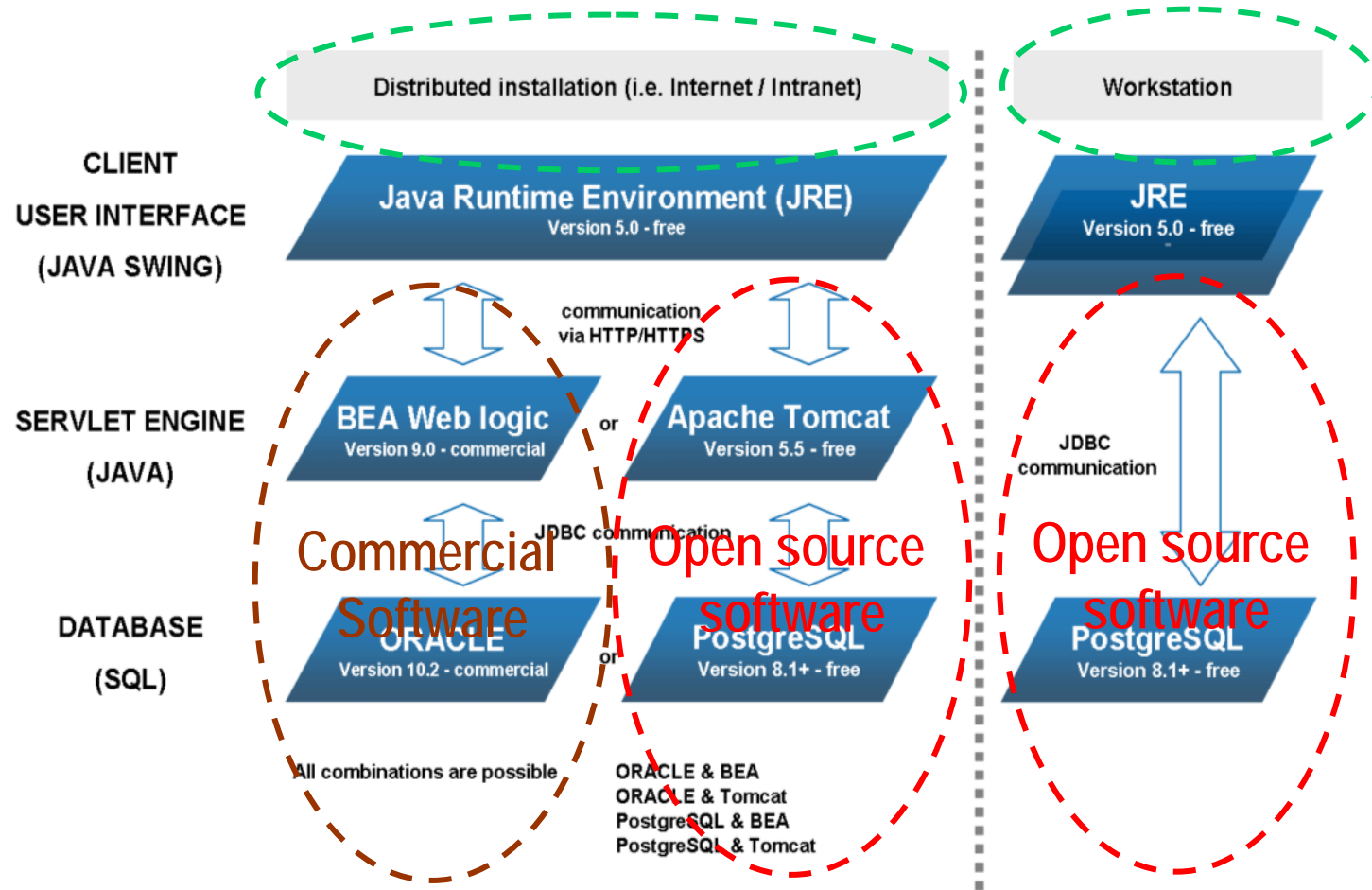
IUCLID 5, the main tool for the Chemical Industry to fulfill their REACH legal obligations, will be released in the coming days

[\[more news...\]](#)

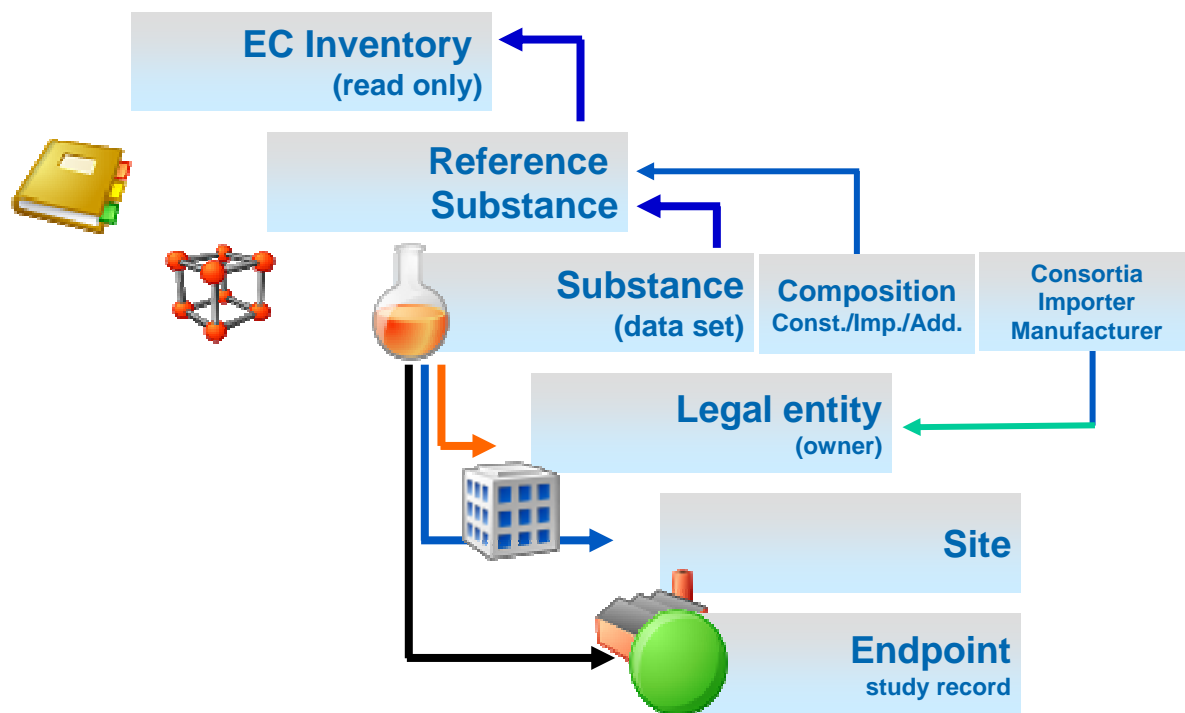
[Legal notice](#)

IUCLID5 System

IT architecture of IUCLID 5 – supported servers



IUCLID 5 Data model



IUCLID5 – 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 and

- 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 distribution
- 5.5 Environmental data
- 5.6 Additional informat

Chapter 6 - Ecotoxicology

- 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 feedingstuffs

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

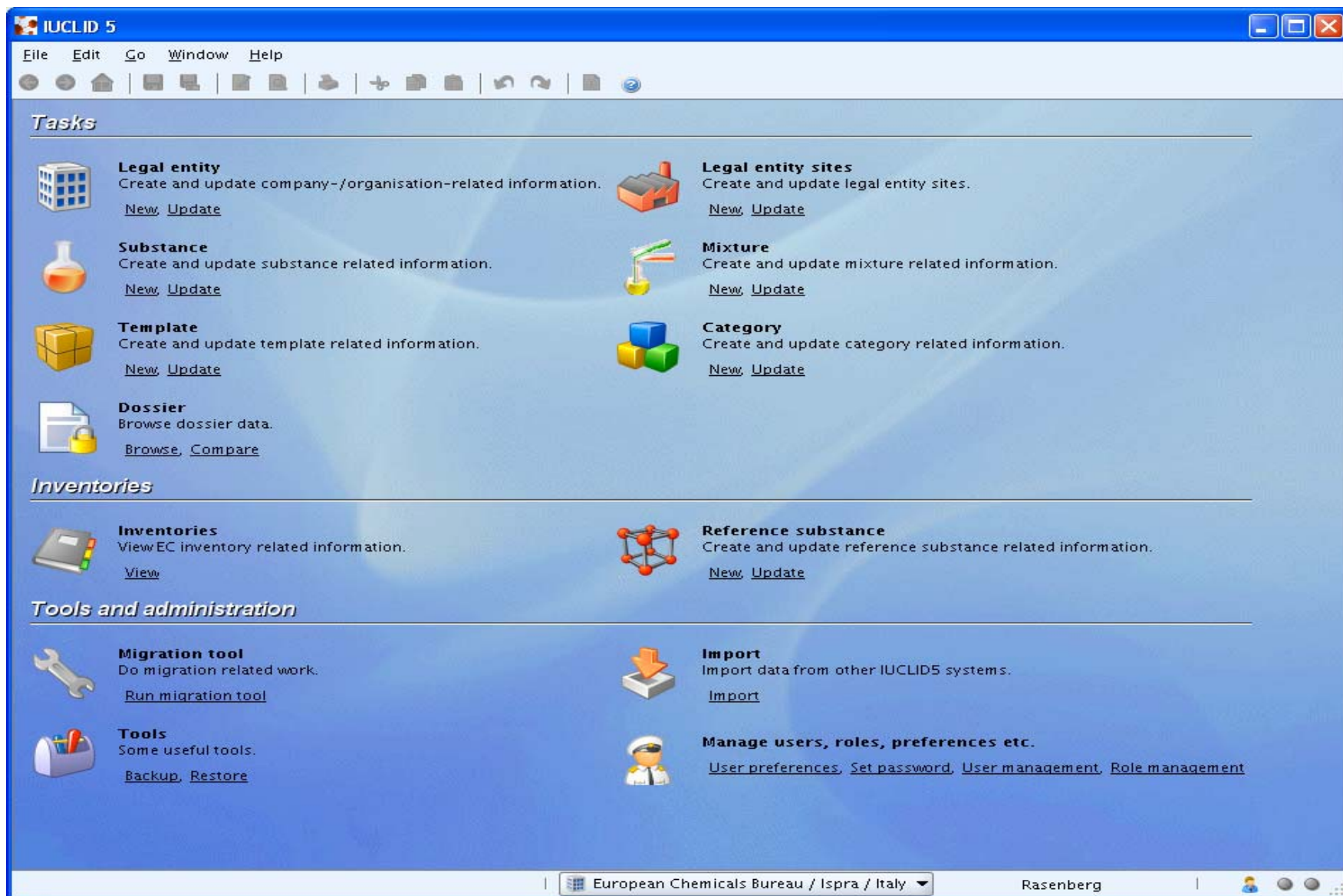
Chapter 10 - Effectiveness against target organisms

Chapter 11 – Guidance on safe use

Chapter 12 – Literature search

Chapter 13 – Assessment Reports

IUCLID5 starting page



The screenshot shows the IUCLID 5 starting page within a web browser window. The window title is "IUCLID 5" and the menu bar includes "File", "Edit", "Go", "Window", and "Help". The interface is organized into three main sections: "Tasks", "Inventories", and "Tools and administration".

Tasks

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

Inventories

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

Tools and administration

- Migration tool**: Do migration related work. [Run migration tool](#)
- Import**: Import data from other IUCLID5 systems. [Import](#)
- Tools**: Some useful tools. [Backup](#), [Restore](#)
- Manage users, roles, preferences etc.**: [User preferences](#), [Set password](#), [User management](#), [Role management](#)

The bottom status bar shows the user is logged in as "Rasenberg" and the system is part of the "European Chemicals Bureau / Ispra / Italy".

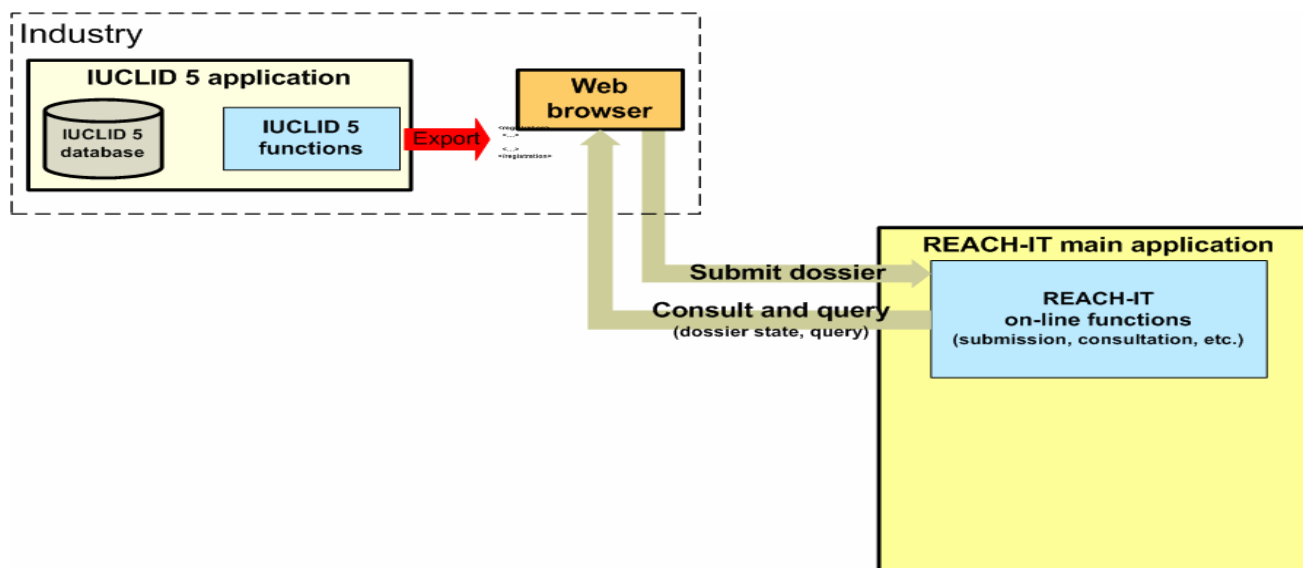
What has to be submitted

Technical dossier + Chemical Safety Report

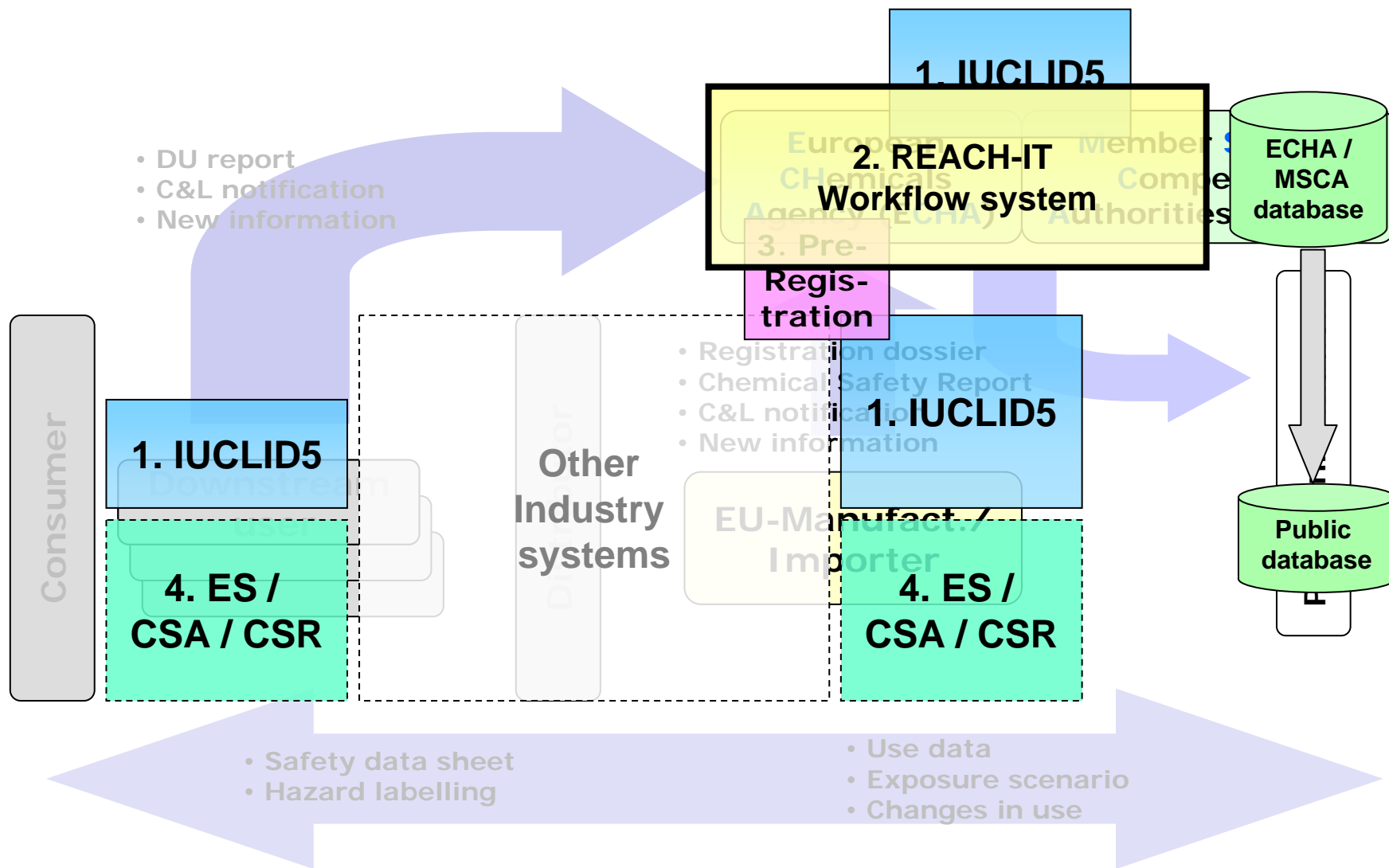
- ❖ Technical dossier (data are filled in IUCLID database)
 - company identity & substance identity
 - manufacture & uses – guidance on safe use - C&L - exposure information if applicable
 - study summaries - robust study summaries - proposals for testing
 - various statements
 - Chemical safety report (> 10 tonnes)
- ❖ Chemical safety report: document (pdf);
 - document created and edited outside IUCLID, but can be incorporated by attachment

From IUCLID 5 to the Agency

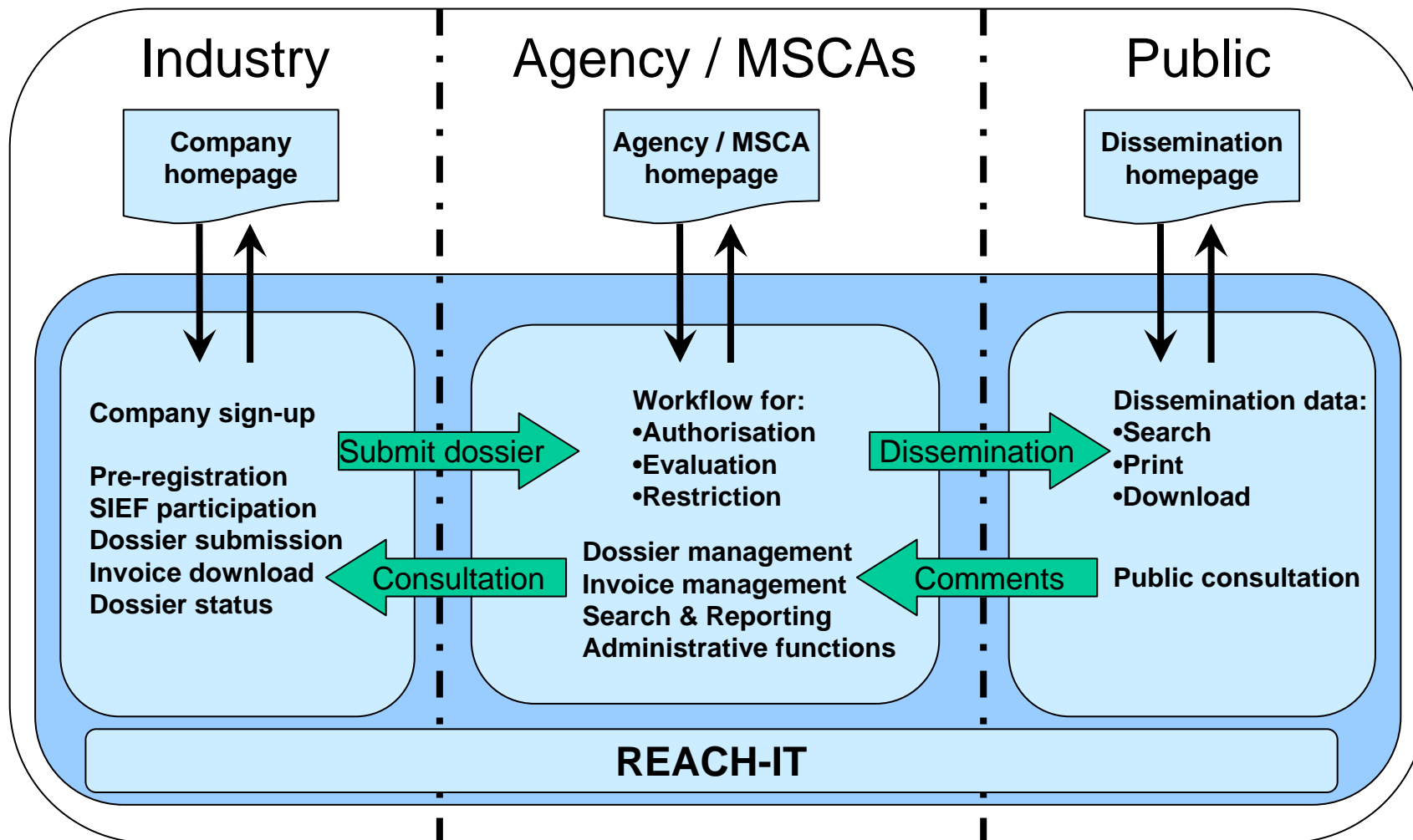
The registration dossier prepared in IUCLID 5 is exported and submitted to the European Chemicals Agency web site (REACH IT)



IT systems developed by EU Commission



REACH-IT overview



REACH-IT vs. IUCLID 5

- ❖ The REACH-IT database will contain the “administrative” information, i.e.
 - Company information, 3rd party representation, joint submission information,...
 - Substance information: identification, tonnages, uses, list of (robust) study summaries contained in the dossier, etc...
 - Dossier information: type of dossier, submission date and number,
 - Follow-up of dossiers (e.g. examination of testing proposals, dossier compliance, ...)
 - C&L inventory
 - Community rolling plans & substance under evaluation
 - Granting of authorisations, etc.

Submission & types of dossier

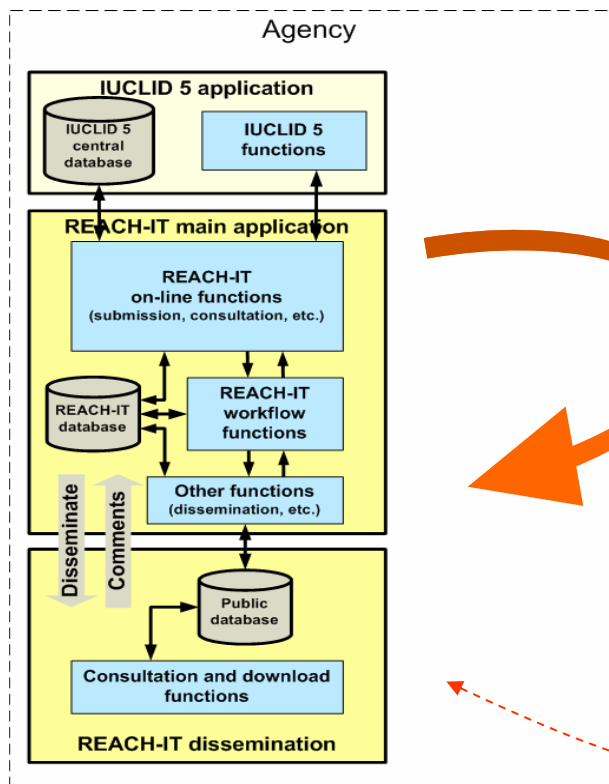
- ❖ Dossiers prepared in IUCLID 5 only
 - Registration dossiers (general case, intermediate, substance in articles, lead/member of a joint submission)
- ❖ Dossiers prepared in IUCLID 5 or in REACH-IT
 - PPORD, C&L notification, Notification of substance in article, DU report, Application for authorisation
 - Pre-registration
module will be prepared after roll-out, delivered as a plug-in
- ❖ Dossiers prepared in REACH-IT only
 - Inquiry, DU notification

What happens after dossier submission?

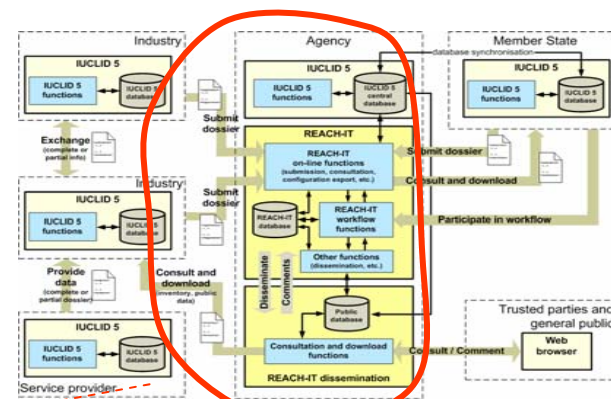
- ❖ After **validation** steps, the registration dossier is stored in the IUCLID 5 database of the European Chemicals Agency
- ❖ The dossier undergoes a **completeness check** process, **an invoice** is generated and forwarded to the registrant
- ❖ Once the dossier is complete and the fee is paid, the **registration number** is sent to the registrant
- ❖ The **registration number** is the identifier for further correspondence. It can and **should be included** in the company's own IUCLID system.

Dissemination

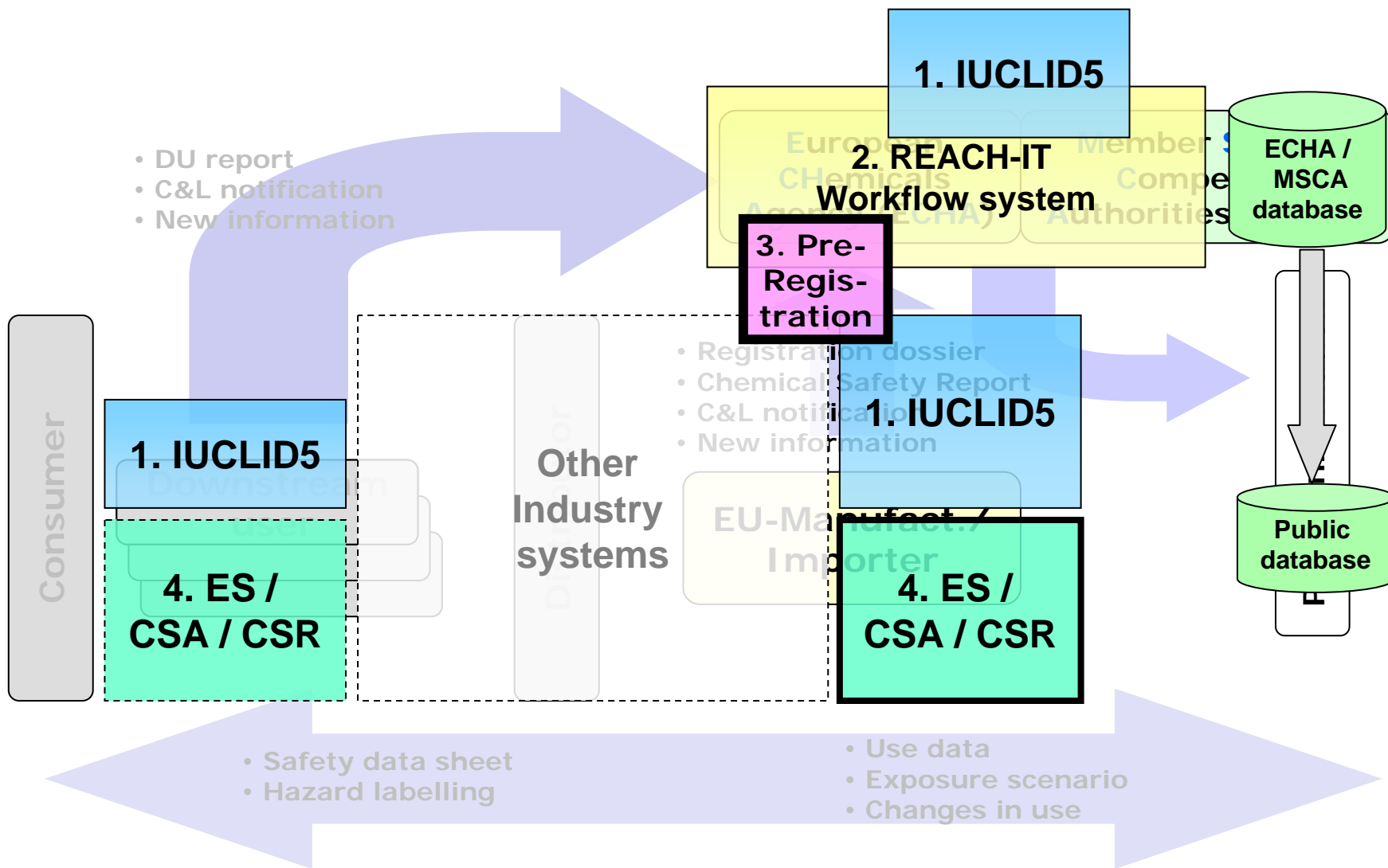
❖ From central IUCLID 5 to REACH-IT dissemination



Selected data from the registration dossier (*based on REACH text, non CBI data*) are disseminated to the REACH-IT dissemination website (= Public database)



IT systems developed by EU Commission



Further IT Tools

- ❖ Beyond IUCLID and REACH IT further IT Tools will be developed to facilitate the work
 - Pre-registration tool
 - Exposure tool (ES)
 - Tool for preparing Chemical Safety Assessment/ Report (CSA/CSR)
- ❖ These tools are elaborated by EU commission (e.g. RIP 3.2-2 Task III9)
- ❖ Supplementary industry needs certain links to their own systems (e.g. SAP-EHS, Atrion, own data bases, MSDS systems)

Pre-Registration

- ❖ On-line entry of Pre-Registration at the REACH-IT WF system
- ❖ Batch submission of data for Pre-Registration:
 - Data may come from different sources, i.e. IUCLID5, Excel, other systems
 - Compliant with standard (XML schema) data requirements
 - EU COM will develop 'add-on module' to extract Pre-registration data from IUCLID5
- ❖ Limited set of data
 - Substance Name
 - Substance IDs. (EINECS, CAS no)
 - Company Name / Address / Contact Person
 - Tonnage band / deadline for registration
 - 3rd Party representative
 - Substances with similar intrinsic properties

IT systems for ES / CSA / CSR

IT tools to support the creation of

- ❖ Exposure scenarios (preliminary / final)
- ❖ Chemical Safety Assessment, including e.g.
 - Estimating modelling
 - Risk Characterisation
 - Chemical Safety Report

It includes:

- Capturing data for ES (e.g. Determinants)
- Estimating modeling tools for Workers, Consumers, Environment
- Standard libraries for e.g. Phrases, RMM ...
- Compilation of Chemical Safety Report
- Shifting data from IUCLID to CSR
- Providing Exposure Scenarios to be annexed to SDS

Schedule:

- ❖ Analysis until end of 2007
- ❖ Building Phase 2008