EUROPEAN COMMISSION
DIRECTORATE-GENERAL
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Developing a registration dossier with IUCLID

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ihcp

Outline

What is IUCLID?

Preparing a registration dossier with IUCLID 5

The registration dossier is ready: what comes next?

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REACH & IUCLID: which link? (1)

- Art. 110 of the REACH proposal specifies:
  - "The Agency shall specify formats and make them free of charge, and software packages and make them available on its website for any submissions to the Agency"
  - "For the purposes of registration, the format of the technical dossier referred to in Article 10(a) shall be IUCLID"

REACH & IUCLID: which link? (2)

- IUCLID is the IT system (software & database)

  - designed to prepare REACH-compliant registration dossiers to be submitted to the European Chemicals Agency
  - it will be made available to Industry free of charge

What is IUCLID?

- IUCLID is a database system for managing hazard data on chemical substances and reporting to the Authorities
- It was initially developed in 1993 to meet the EU requirements of the Existing Substances Regulation (793/93/EEC)
- New version IUCLID 5 in development: major upgrade of IUCLID 4, both in technology and functionality
- Data format agreed at international level (OECD format) – The same pool of data stored in IUCLID can be re-used for other legislations
- Will come with a migration tool to transfer existing data to the new format

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What is meant by registration dossier?

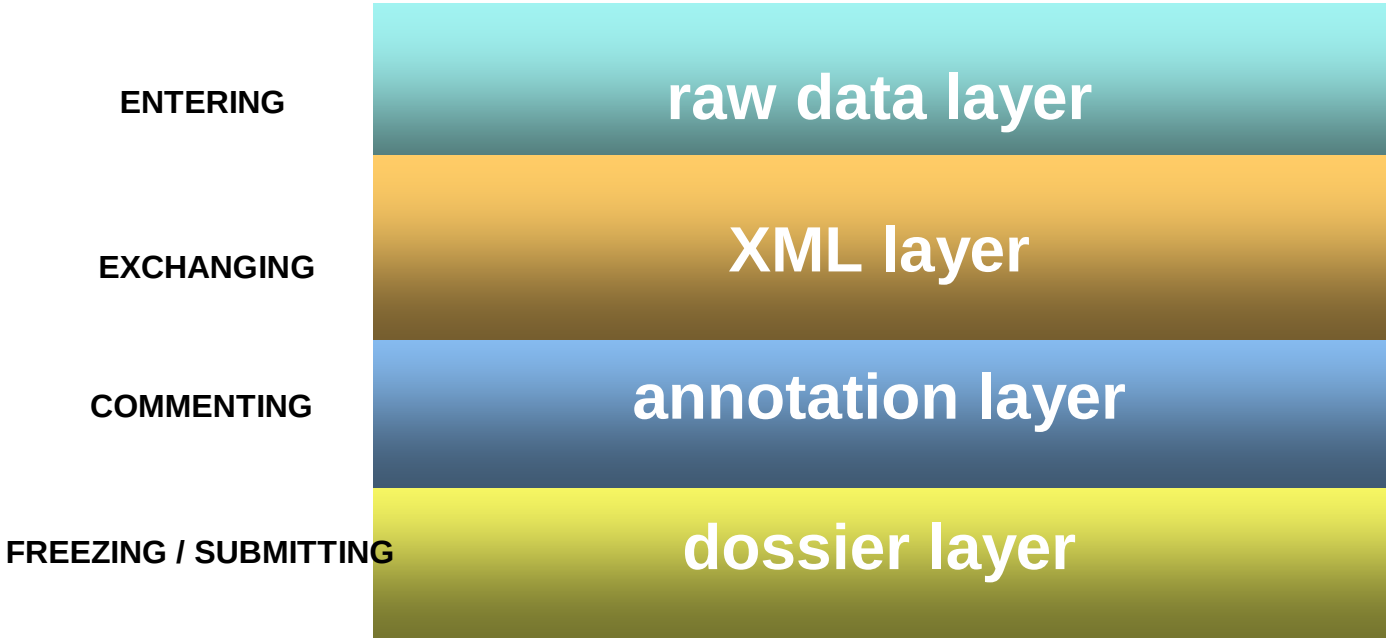
- Requirements are defined in Art. (10) of the REACH proposal
  - Technical dossier
    - company identity & substance identity
    - manufacture & uses – guidance on safe use - C&L - exposure information if applicable
    - study summaries - robust study summaries - proposals for testing
    - various statements
  - Chemical safety report (>10 tonnes)

- Technical dossier: database format
  - data are filled in a structured format in the IUCLID database
- Chemical safety report: document (e.g. MS Word);
  - document created and edited outside IUCLID

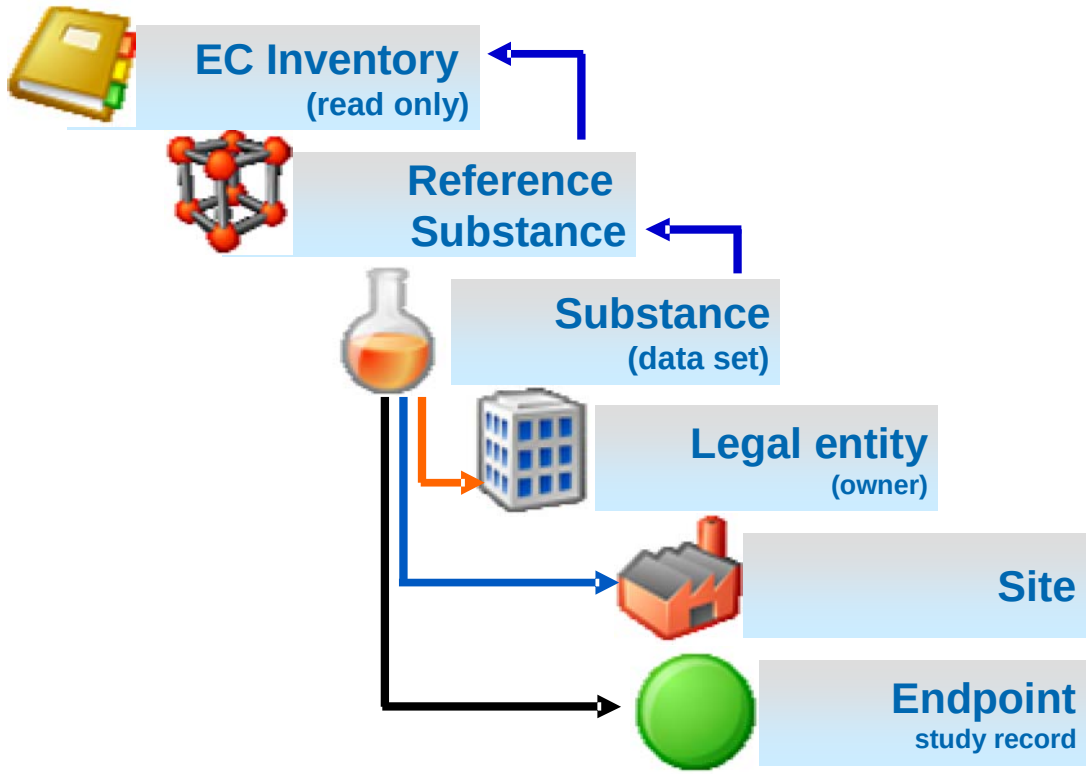
One single package to be submitted to Agency

Preparing the registration dossier

- Step wise approach:
  - from data collection via manual data entry or electronic exchange with other applications e.g. MSDS, EH&S systems, …data review and commenting,
  - to selection of relevant data to be submitted in the registration dossier
- IUCLID 5 is structured to cover all these steps



IUCLID 5 structure



IUCLID 5 main menu

company information

sites of production or use

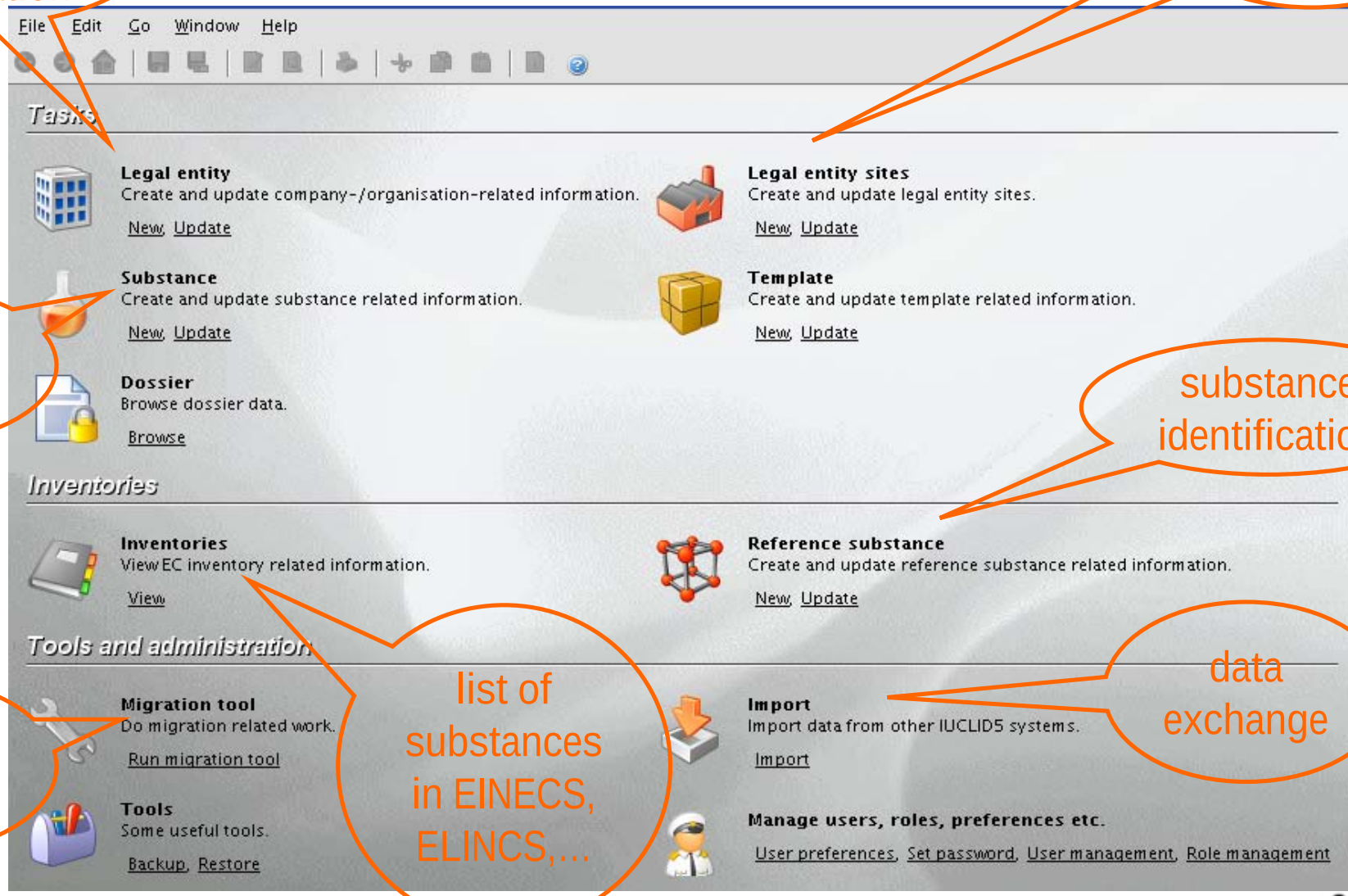
substance properties

substance identification

Migration of existing data

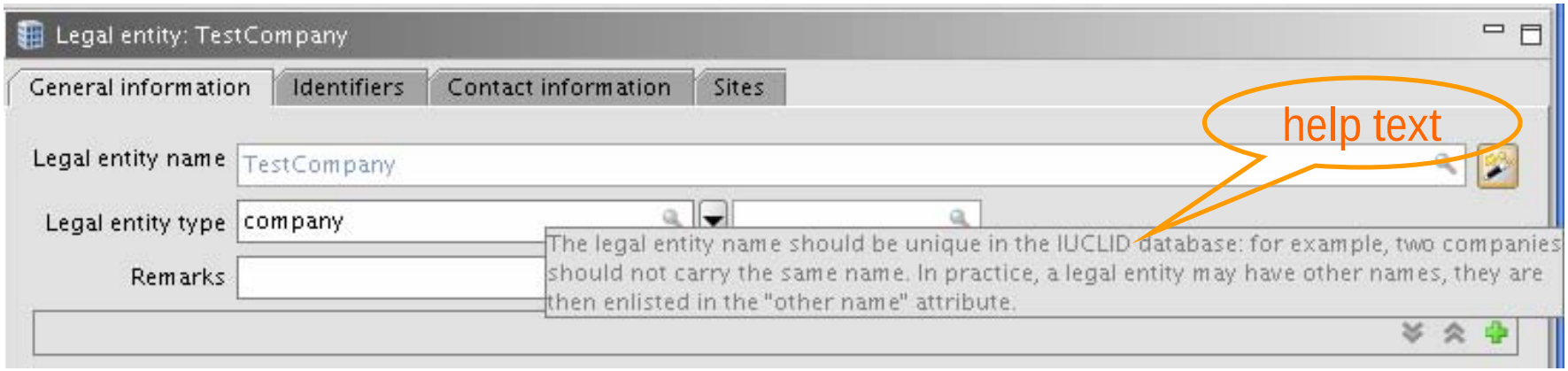
list of substances in EINECS, ELINCS,…

data exchange



Company information

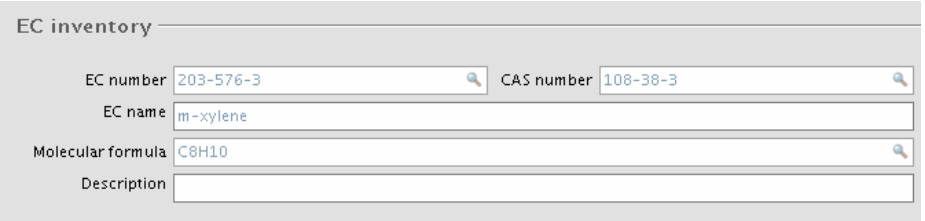
- "Legal entity" = information on manufacturer / importer [Art 10 (a) (i)]



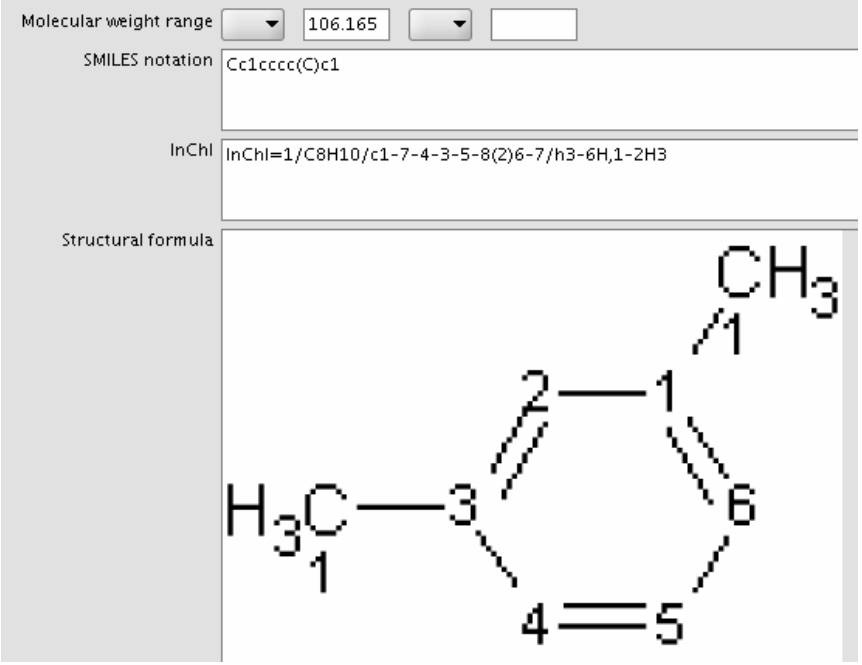
- Company information is stored in a "directory" – interest:
  - Re-usability: the same information can be re-used in all registration dossiers submitted by the company without typing again the information
  - Central management of the information: no inconsistency!
    - updated once for all substances
    - exchanged with partners within a joint submission

Substance identity (1)

- Names, EINECS, ELINCS, or CAS nb, Composition…[Art 10 (a) (ii)]
- Direct link to the EC inventory if the substance is listed



- Structural information



Substance identity (2)

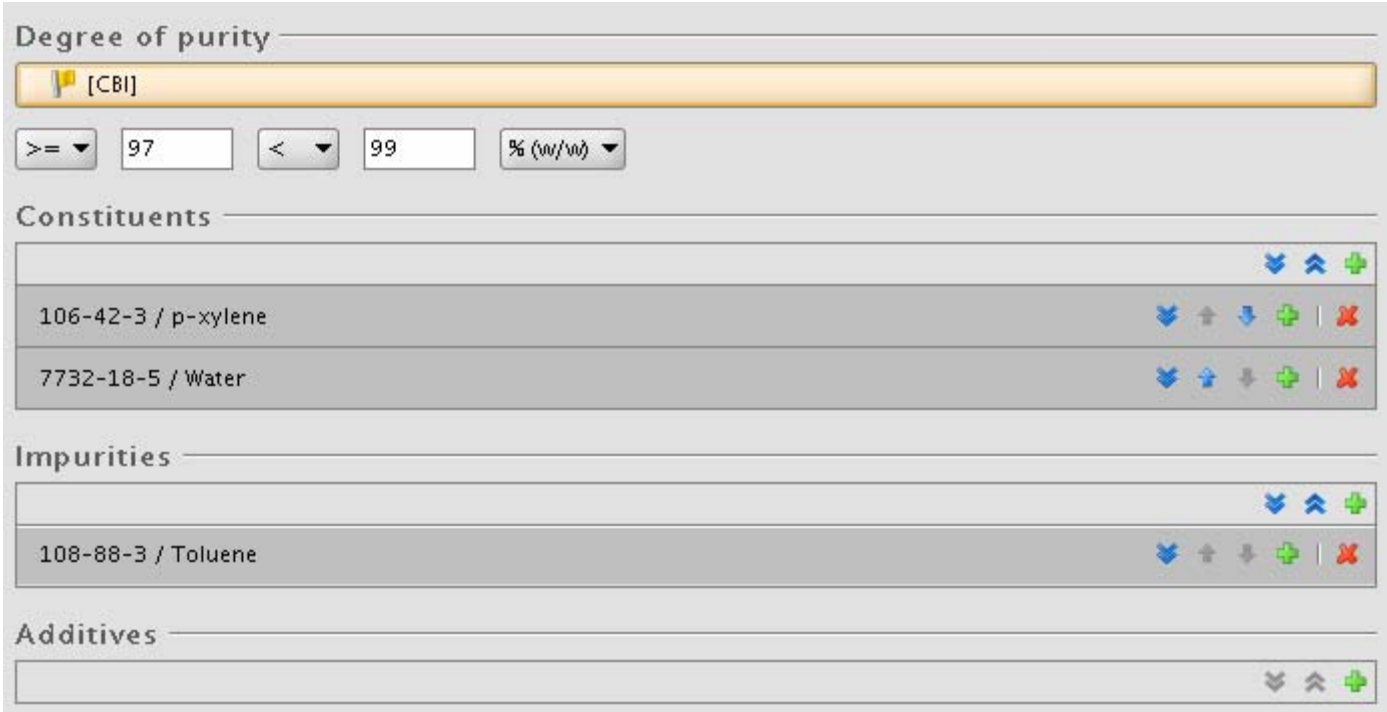
- Composition

confidentiality setting

description of constituents, and %

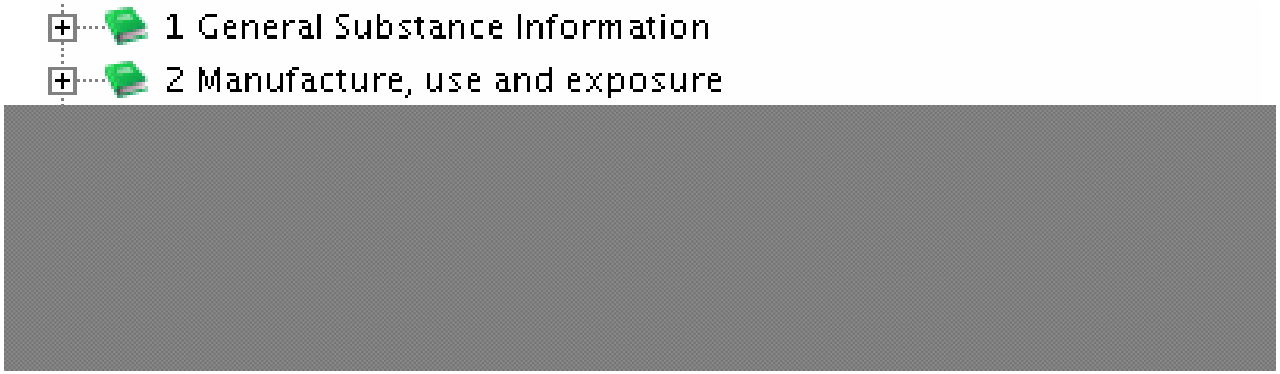
(main) impurities, and %

additives, nature and %

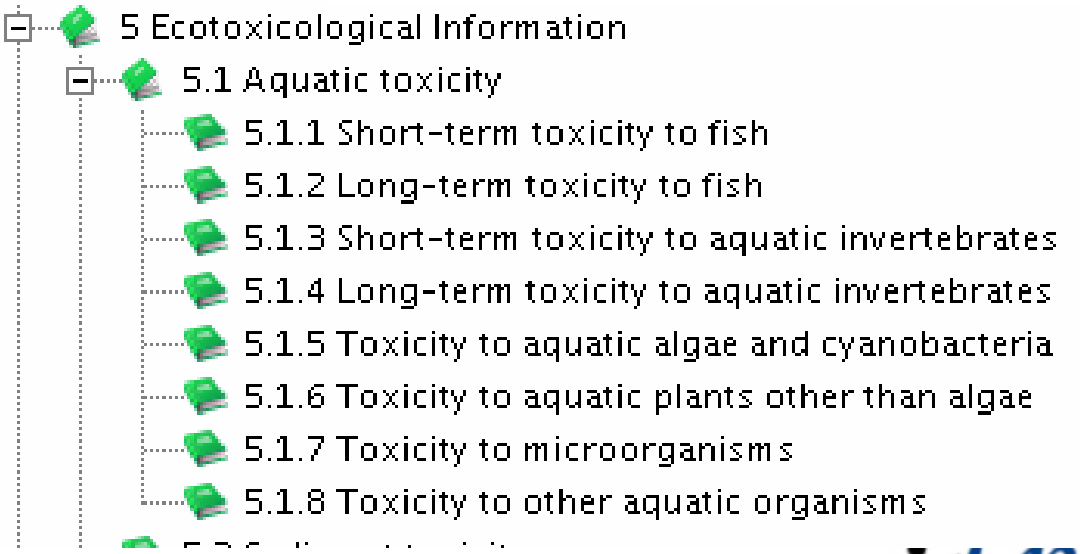


(Robust) study summaries (1)

- Annexes VII to X: from chapter 3 to chapter 7



- Sub-chapters

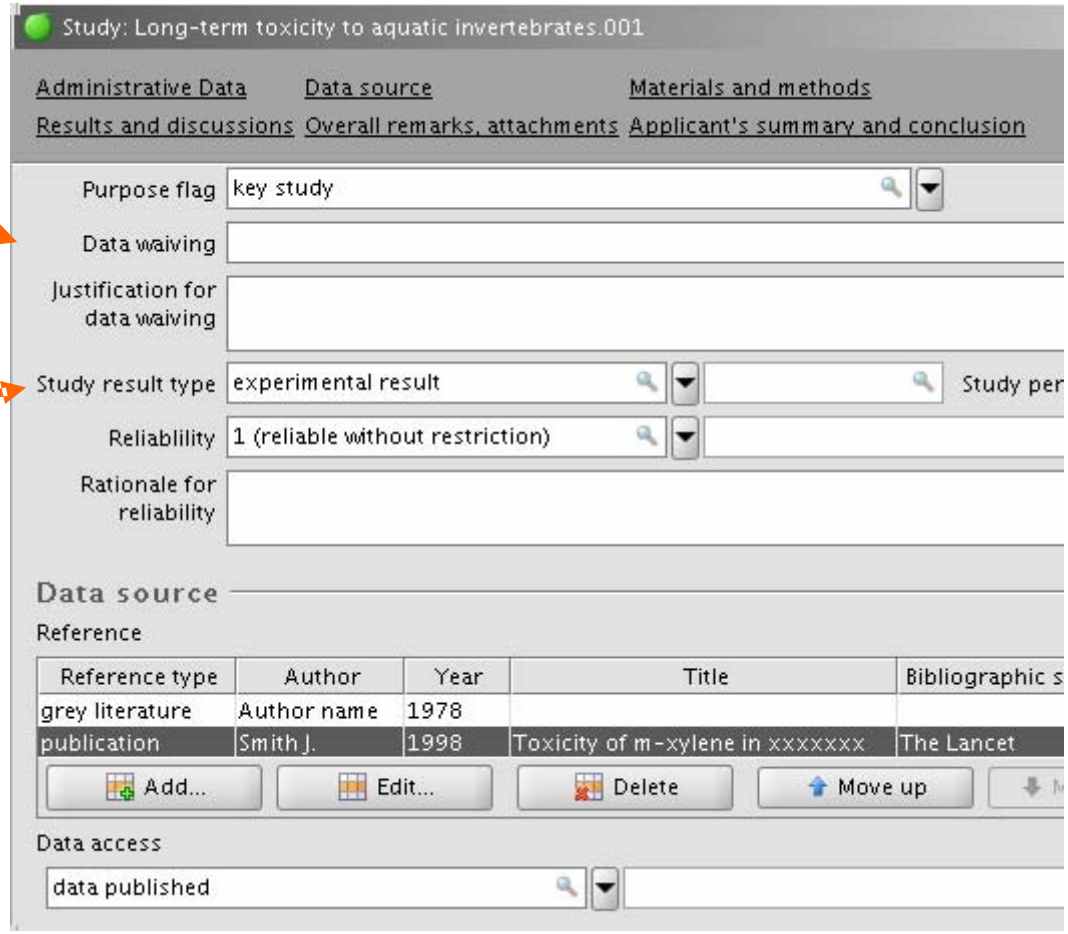


(Robust) study summaries (2)

- Long-term toxicity to aquatic invertebrates (extract)

waiving (annex XI)

experimental result
estimated
read-across
QSAR
...
(annex XI)



(Robust) study summaries (3)

- Conclusions and summaries can be inserted and formatted with a text editor – ready to be exported to the Chemical safety report

Long-term exposure

Dermal DN(M)EL in mg/kg bw/day	DNEL		Assesment Factor	
Inhalation DN(M)EL in mg/m³	DNEL	20	Assesment Factor	10
Oral DN(M)EL in mg/kg bw/day	not quantifiable		Assesment Factor	

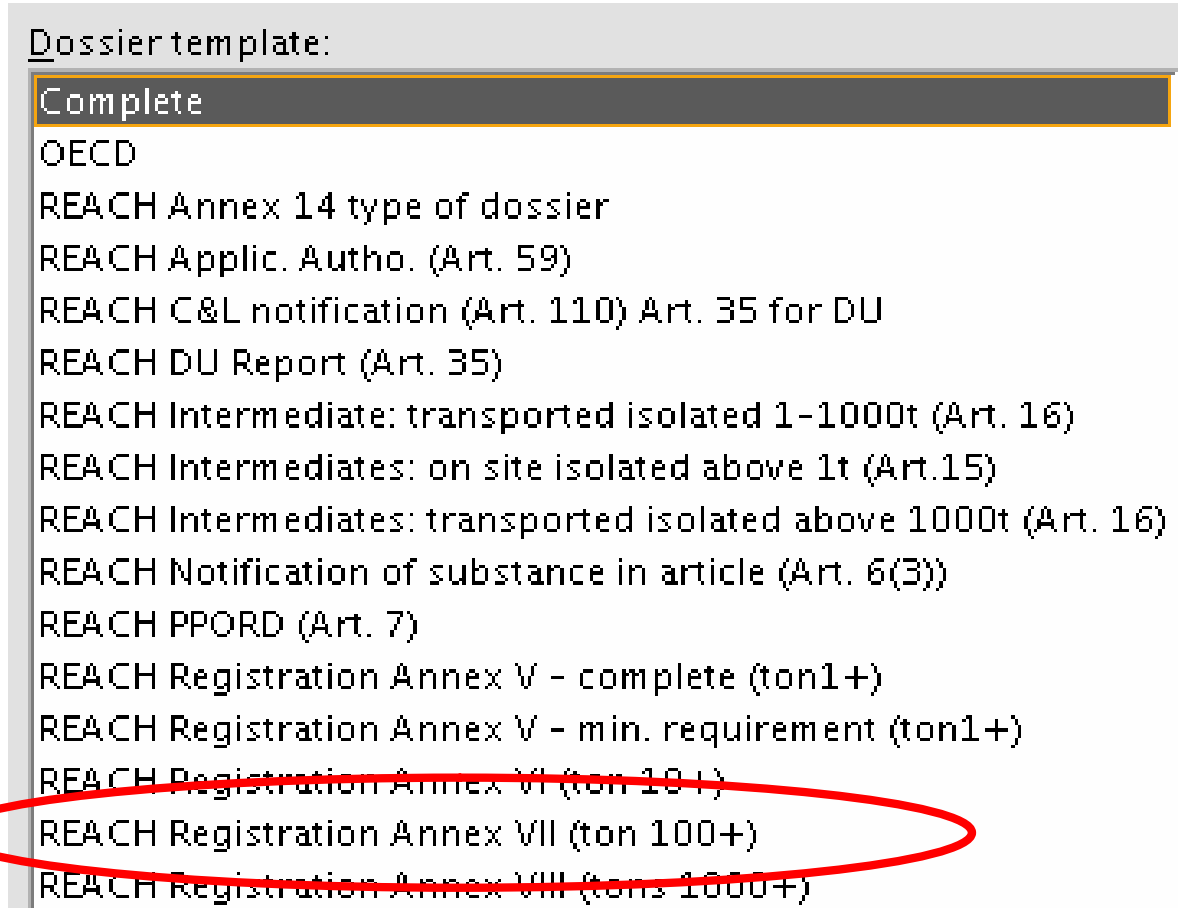
Discussion

Exposure data are available for Scenarios 1, 2 and 3. For Scenario 4, due to the very large panel of use, the EASE model is prefer
model is considered to be the worst case). Occupational exposure data are summarised in the next table.

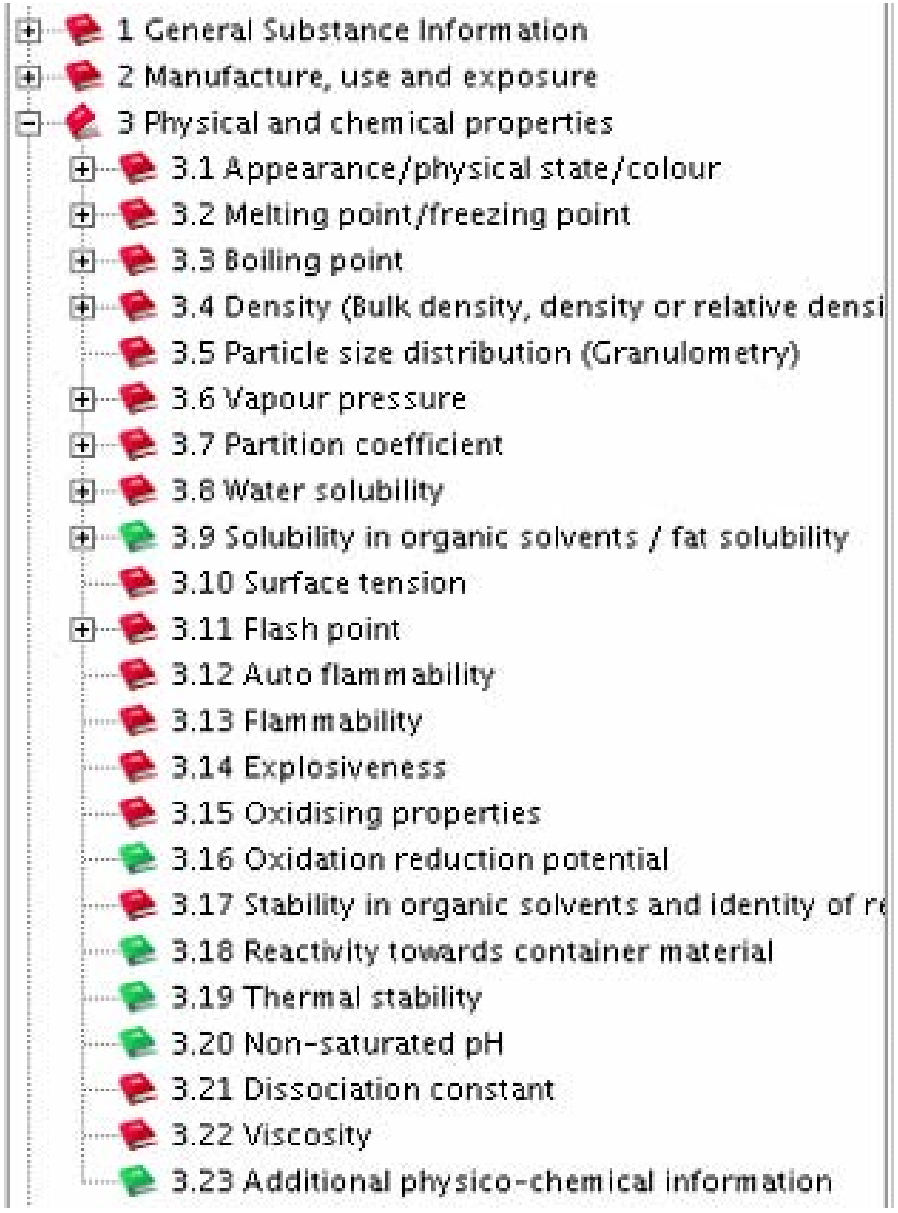
Scenario	Estimated inhalation exposure ppm (mg/m^3)		Estimated skin exposure (mg/cm^2/day)
	Long term (8-hour TWA)	Short term	
1-Production	20 (69)	30 (103)	0-0.1
2-Intermediate	20 (69)	30 (103)	0-0.1
3-Formulation and industrial use of	300 (1,032)		0.03-0.3

Creation of the registration dossier (1)

- The user selects the type of dossier, depending on the tonnage range, in a pre-defined list (picklist)

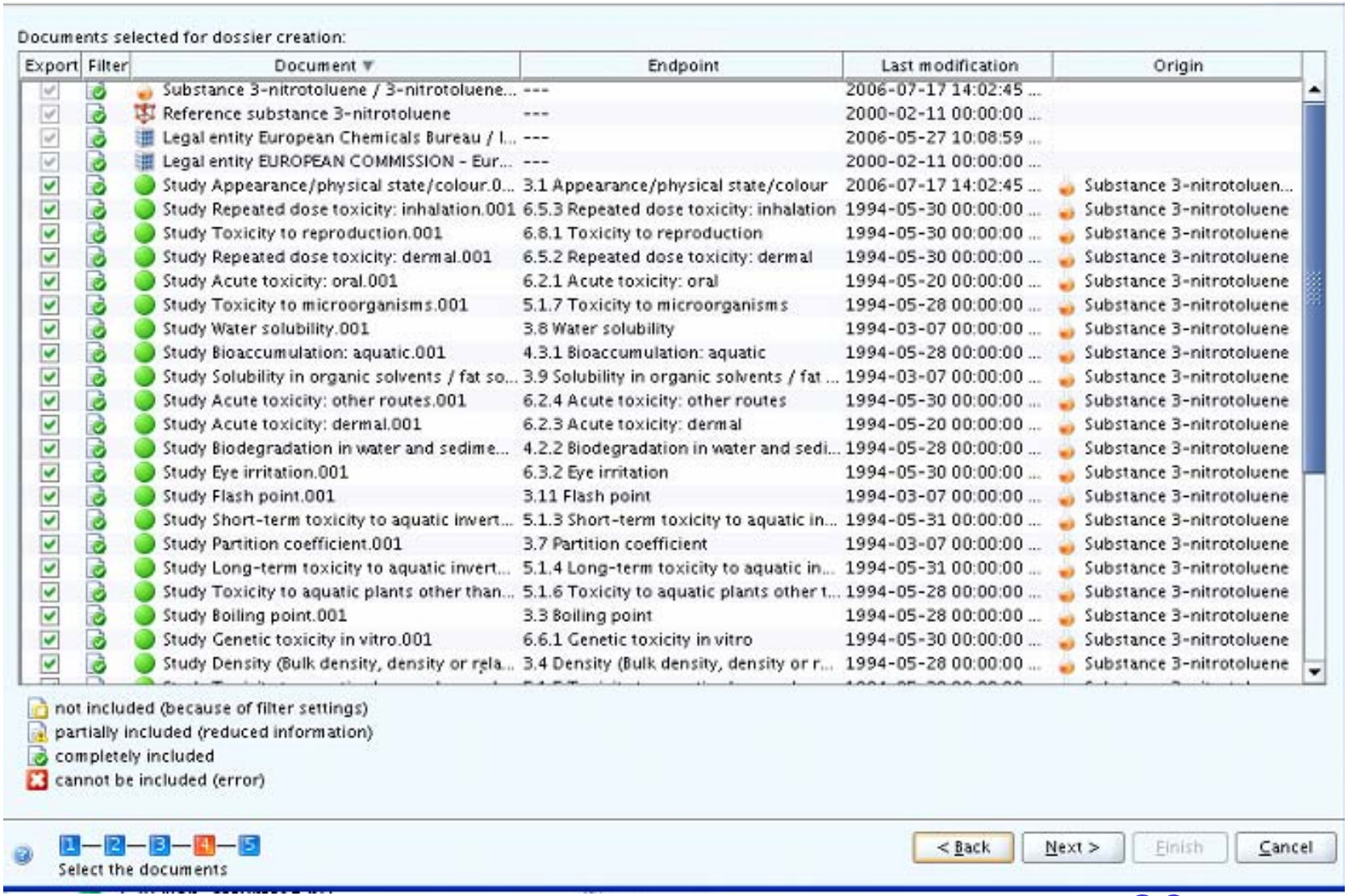


Creation of the registration dossier (2)



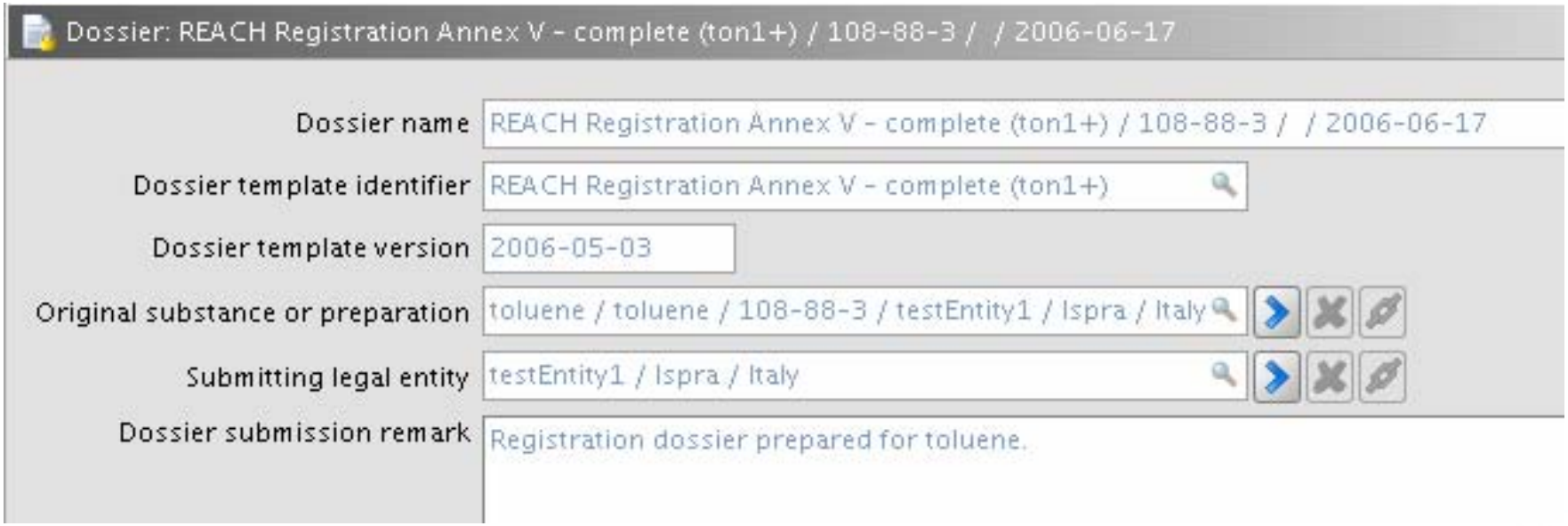
Creation of the registration dossier (3)

- A list gives an overview of the elements that will figure in the dossier



Creation of the registration dossier (4)

- When the selection of the elements of the dossier is complete, the creation process can be finalised
- Data transferred in the dossier are frozen (read-only information)
- The dossier is ready for submission: a summary of its content is displayed



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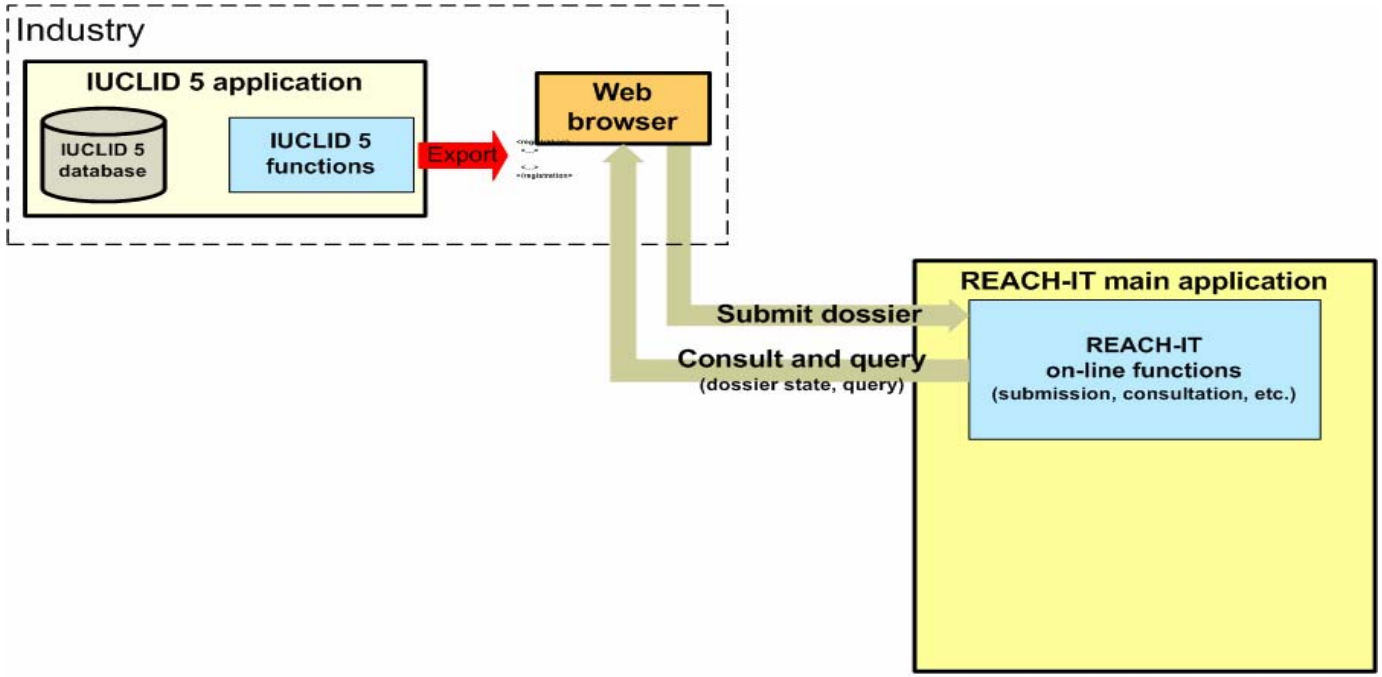
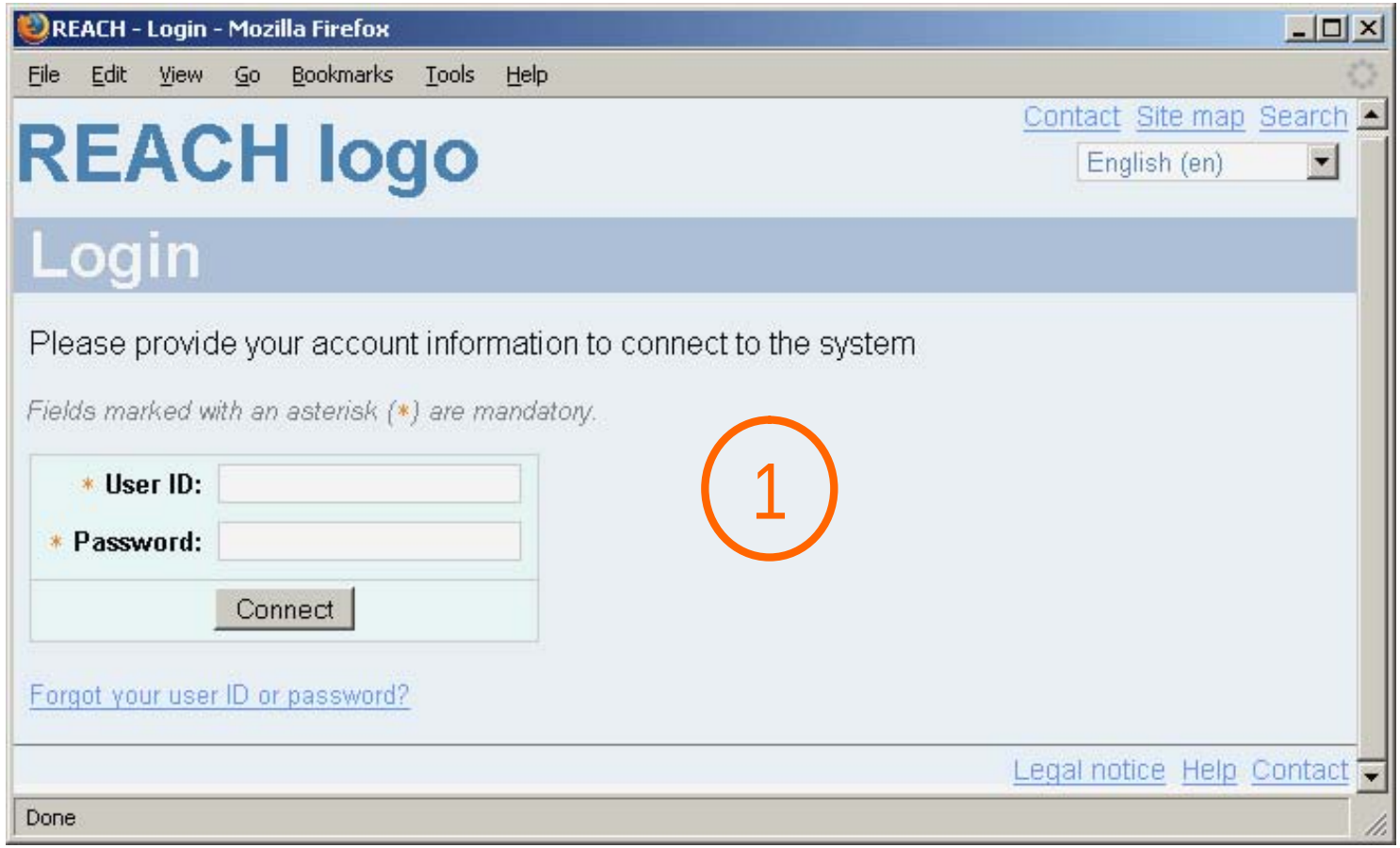
From IUCLID 5 to the Agency

- The registration dossier prepared in IUCLID 5 is exported and submitted to the European Chemicals Agency web site



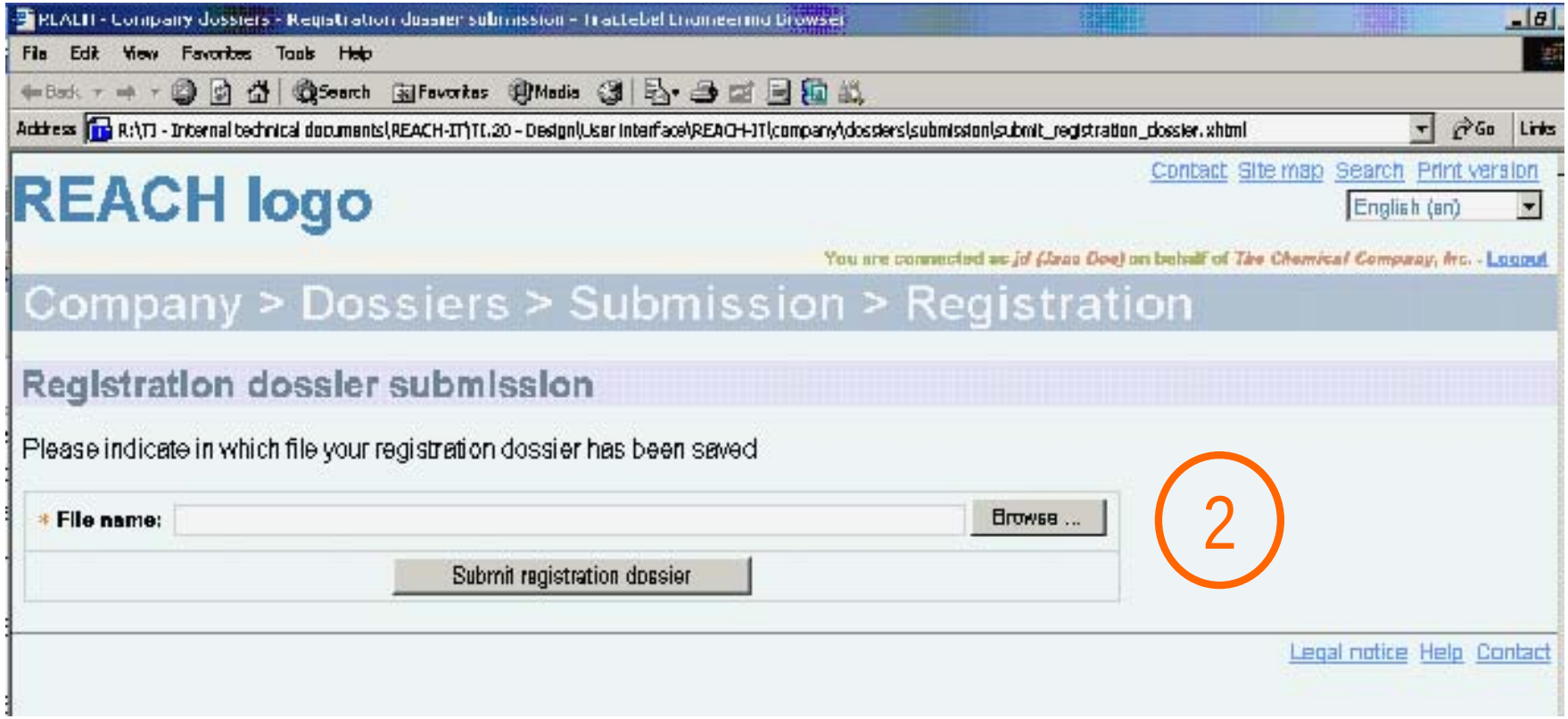
Dossier submission (1)

1. The user connects to the Agency web site and gives his credentials (ID & password)



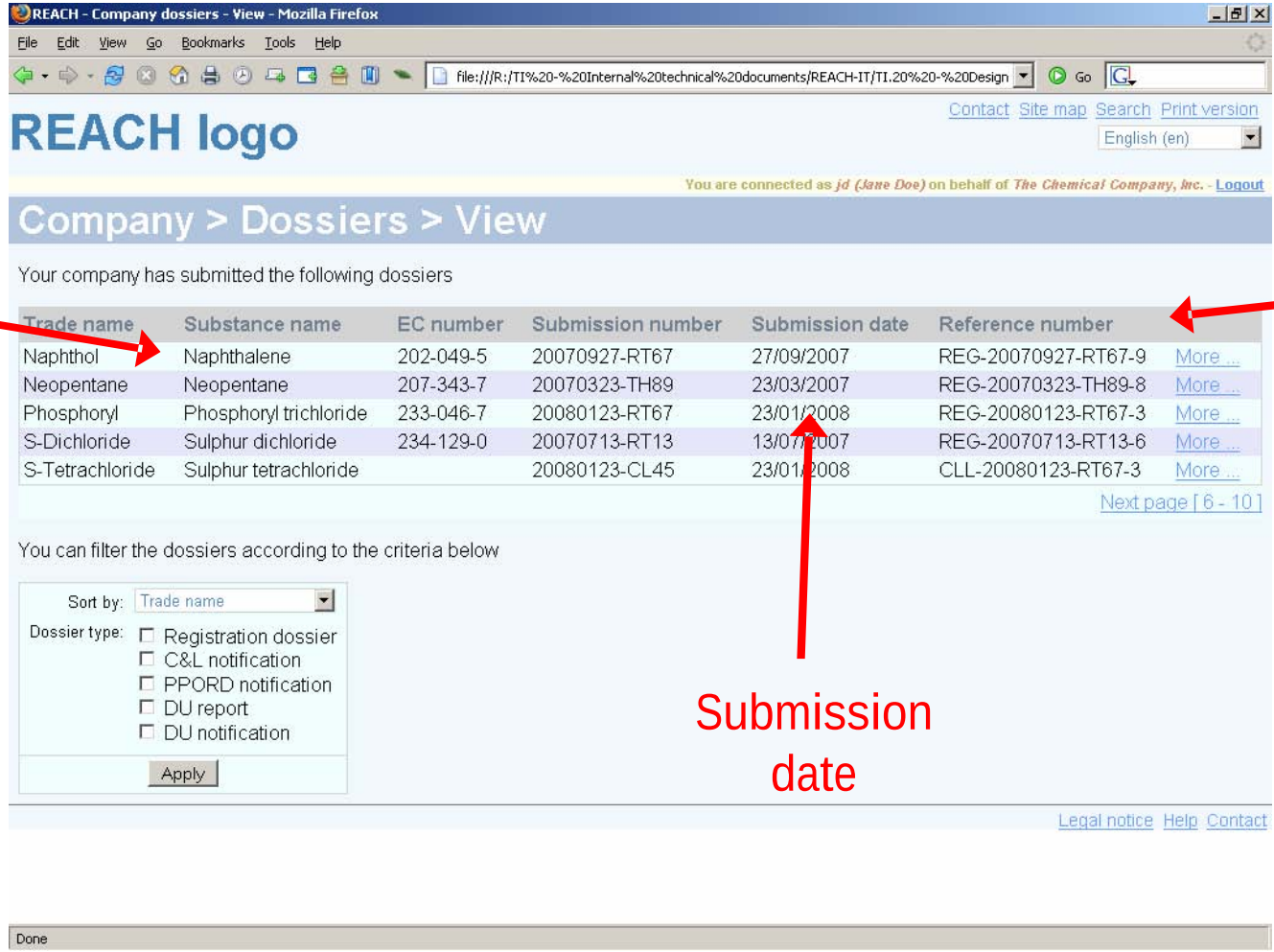
Dossier submission (2)

2. The user then selects the submission page in the home menu, and submits his registration dossier



Dossier follow-up

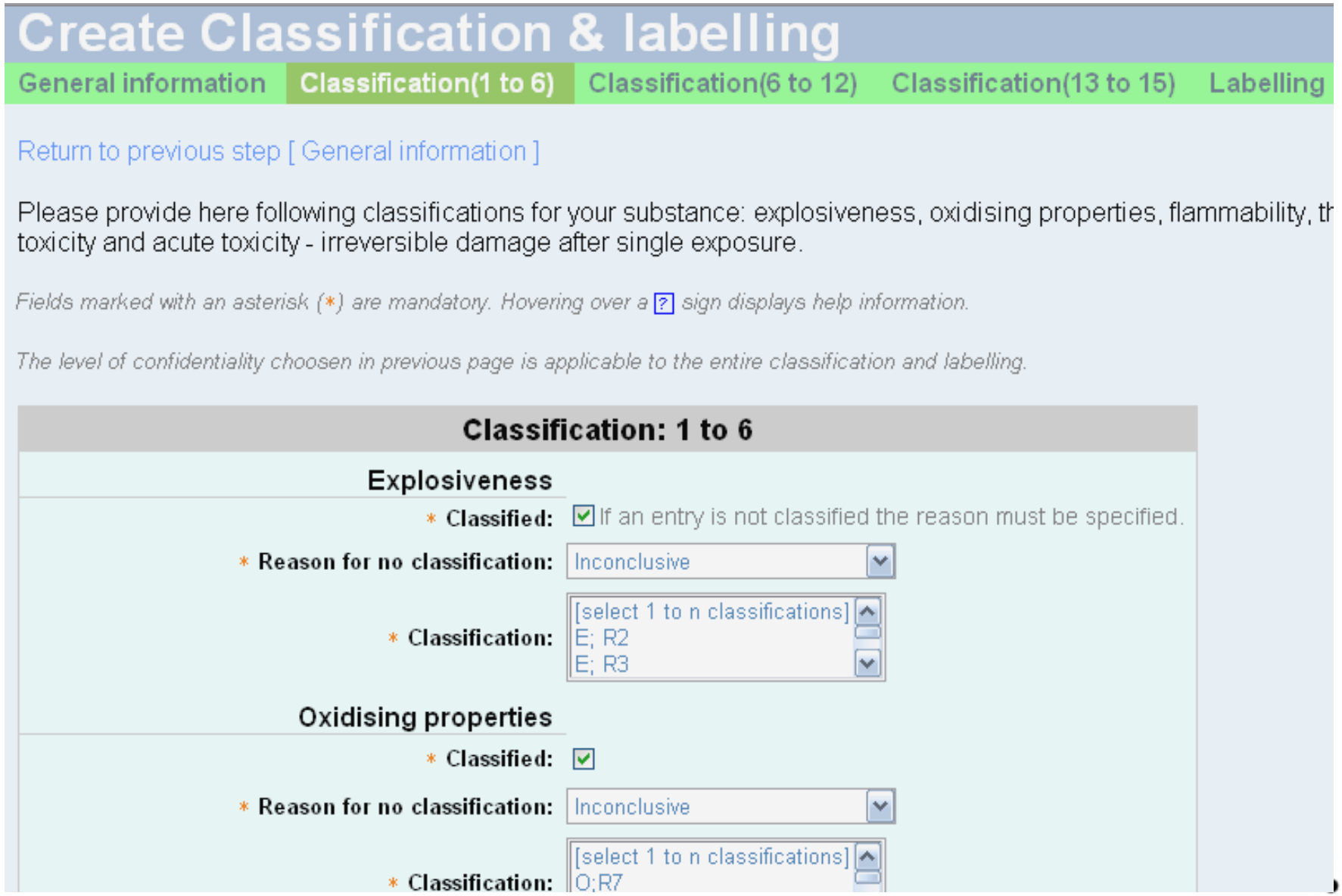
- The user may consult the Agency website to get an overview of his submitted dossiers



Do I always have to use IUCLID?

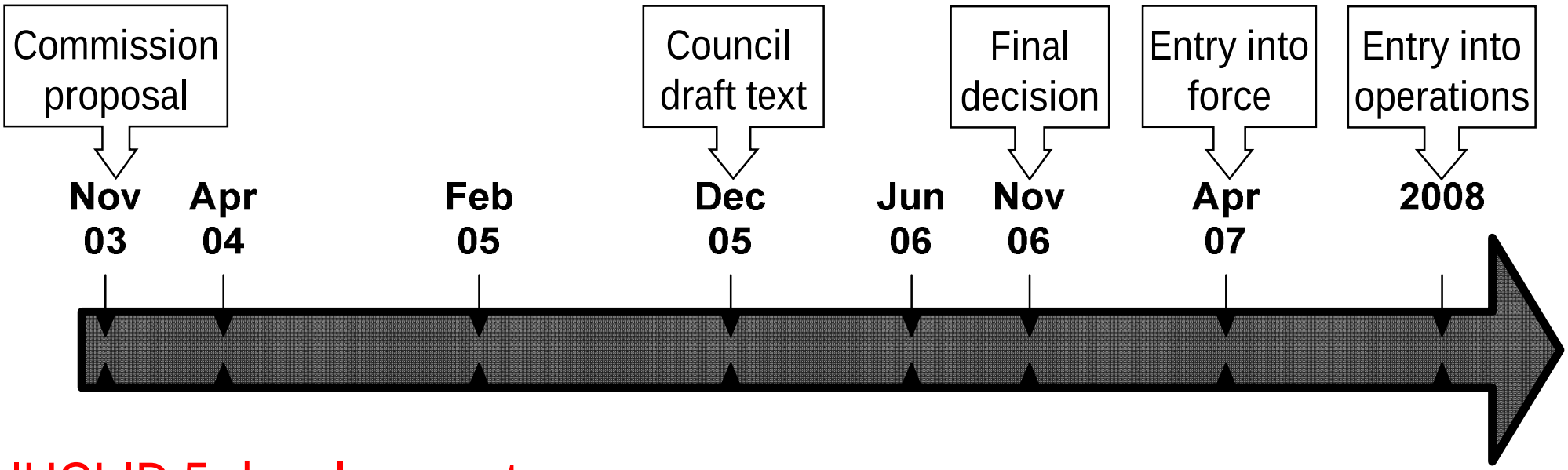
- NO!
- Certain types of “dossiers”, (i.e. C&L notifications, Downstream users reports or notifications, PPORD dossiers, application for authorisation, etc…) are much simpler than the registration dossier
- in particular they contain no (robust) study summaries
- For those dossiers, web-applications will be made available on the Agency web site (i.e. no need to use IUCLID)

C&L notification example



Timeline

Legal framework

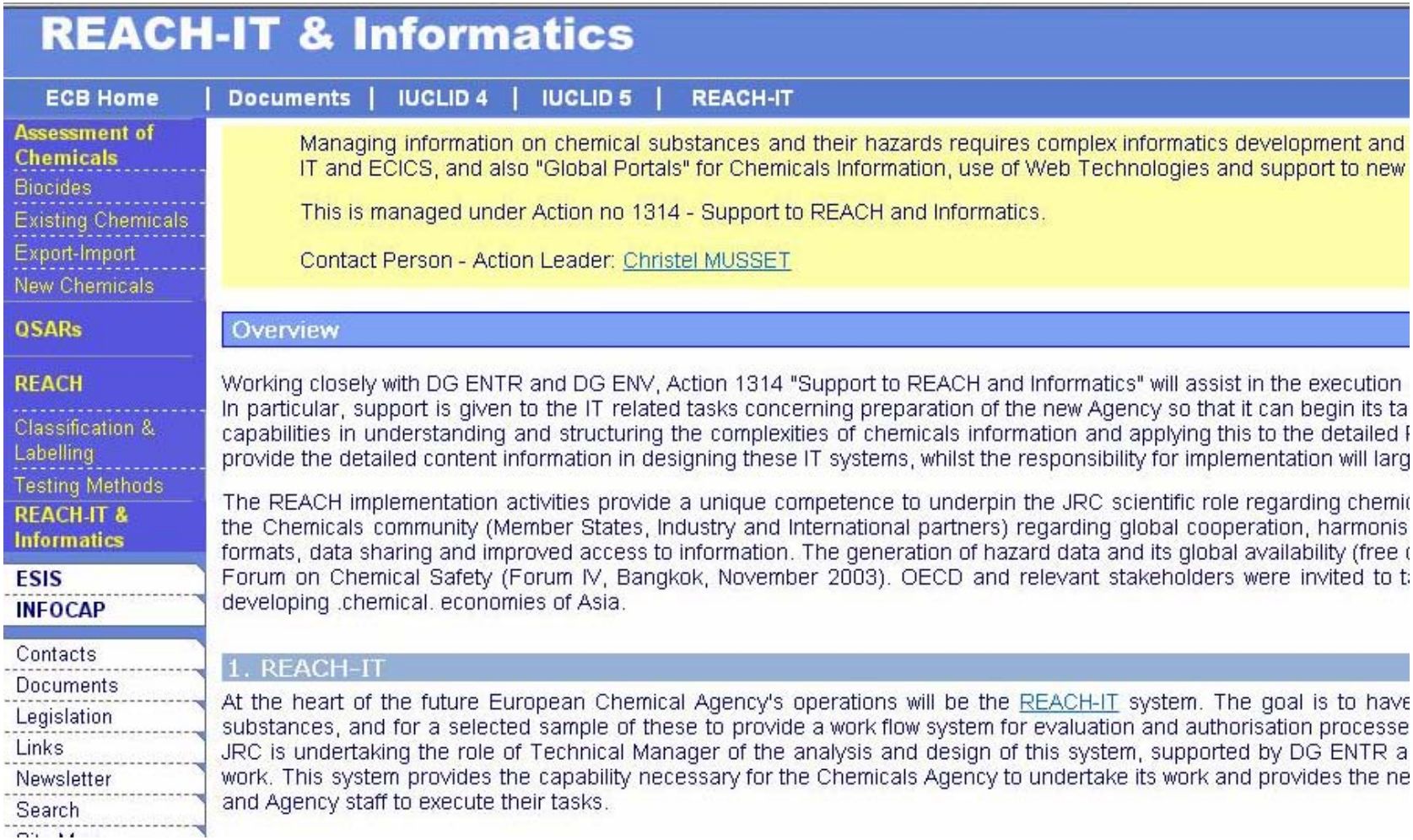


IUCLID 5 development

Business model	Analysis & Design	Build	Roll out

Further information on IUCLID 5

- http://ecb.jrc.it/REACH-IT-INFORMATICS/



REACH-IT & Informatics

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Assessment of Chemicals
Biocides
Existing Chemicals
Export-Import
New Chemicals
QSARs
REACH
Classification & Labelling
Testing Methods
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Managing information on chemical substances and their hazards requires complex informatics development and IT and ECICS, and also "Global Portals" for Chemicals Information, use of Web Technologies and support to new

This is managed under Action no 1314 - Support to REACH and Informatics.

Contact Person - Action Leader: Christel MUSSET

Overview

Working closely with DG ENTR and DG ENV, Action 1314 "Support to REACH and Informatics" will assist in the execution In particular, support is given to the IT related tasks concerning preparation of the new Agency so that it can begin its ta capabilities in understanding and structuring the complexities of chemicals information and applying this to the detailed provide the detailed content information in designing these IT systems, whilst the responsibility for implementation will larg

The REACH implementation activities provide a unique competence to underpin the JRC scientific role regarding chemi the Chemicals community (Member States, Industry and International partners) regarding global cooperation, harmonis formats, data sharing and improved access to information. The generation of hazard data and its global availability (free Forum on Chemical Safety (Forum IV, Bangkok, November 2003). OECD and relevant stakeholders were invited to t developing .chemical. economies of Asia.

1. REACH-IT

At the heart of the future European Chemical Agency's operations will be the REACH-IT system. The goal is to have substances, and for a selected sample of these to provide a work flow system for evaluation and authorisation processe JRC is undertaking the role of Technical Manager of the analysis and design of this system, supported by DG ENTR a work. This system provides the capability necessary for the Chemicals Agency to undertake its work and provides the ne and Agency staff to execute their tasks.