Overview on IUCLID and dossier creation

19 October 2012

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Content

- What is IUCLID and where to find it
- Structure and main elements
- Filling in the substance dataset
- Creating and exporting a dossier

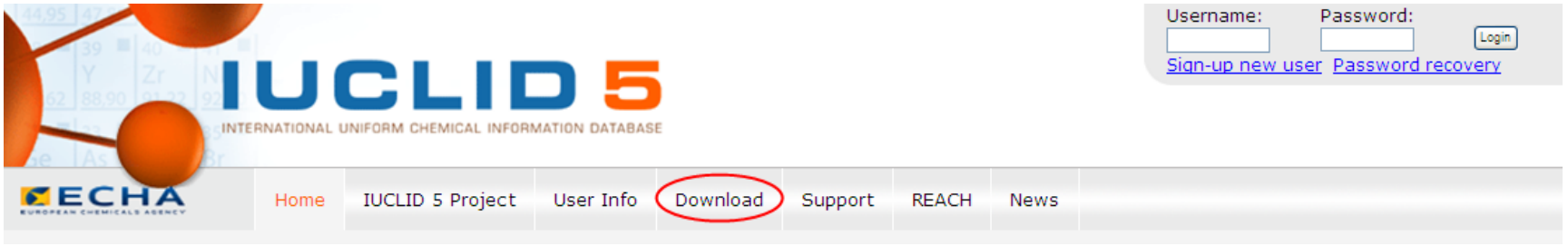
What is IUCLID 5 and where to find it

What is IUCLID 5

- IT application built to collect, store, maintain and exchange information on the intrinsic and hazardous properties of chemicals;
- Designed to serve this purpose for both REACH and other chemical legislatory programmes (e.g. OECD HPV Chemicals and EU BPD);
- Key tool for the chemical industry in fulfilling their obligation to submit data to ECHA under REACH;
- Used by ECHA and MSCAs to evaluate data submitted by industry.

Where to get IUCLID 5

IUCLID 5 is available free of charge on the IUCLID 5 website at http://iuclid.eu



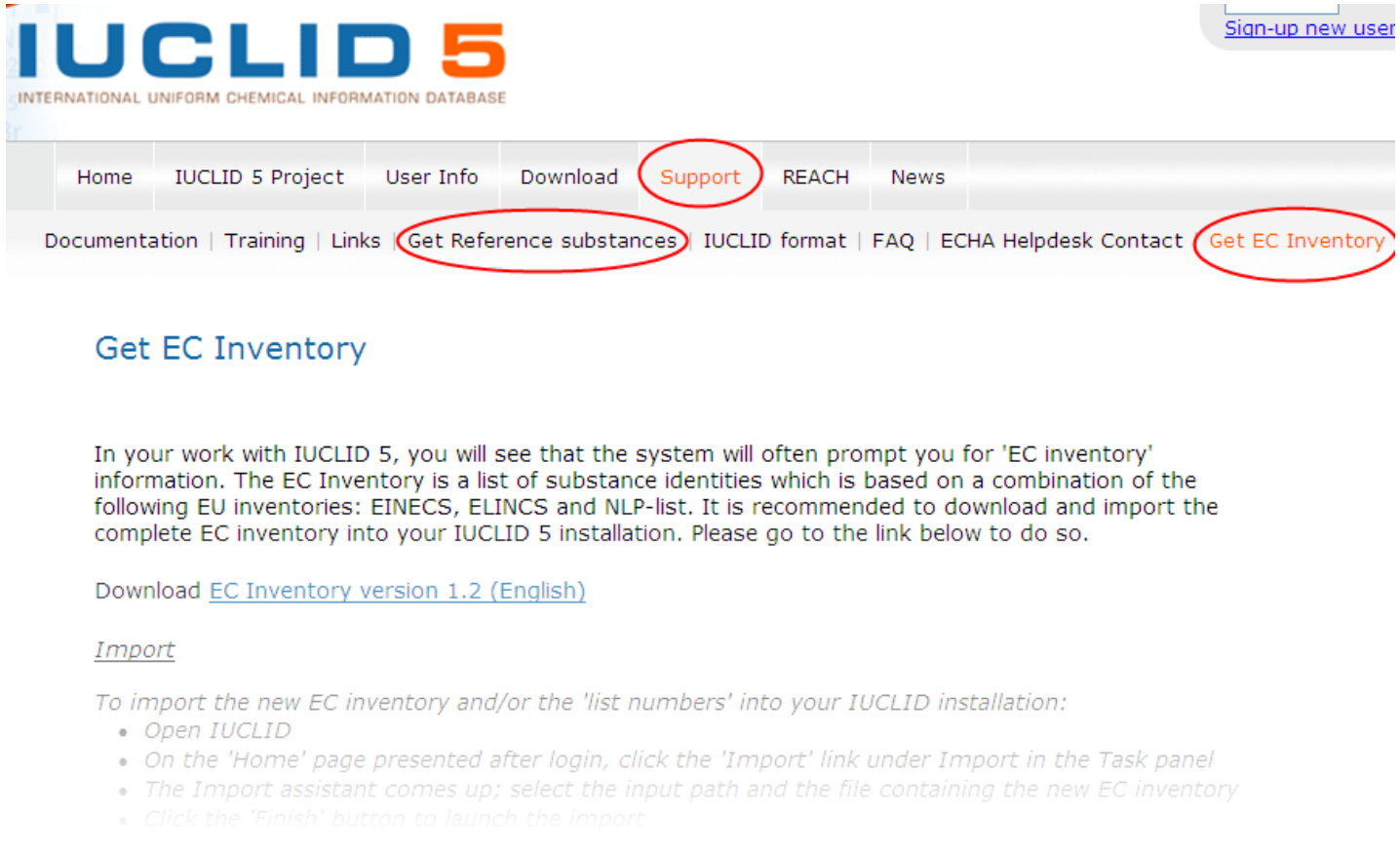
also accessible via the ECHA website

Download

IUCLID 5
INTERNATIONAL UNIFORM CHEMICAL INFORMATION DATABASE
ECHA
Home
IUCLID 5 Project
User Info
Download
Support
REACH
News
Version 5.4 | Version 5.3 | Version 5.2 | Version 5.1.1 | Web Services | Archive
Stand-alone version 5.4.0
Distributed version 5.4.0
CSR Plug-in
Dissemination Plug-in
Fee Calculation Plug-in
Help System Plug-ins
Query Plug-in
Technical Completeness Check (TCC) Plug-in

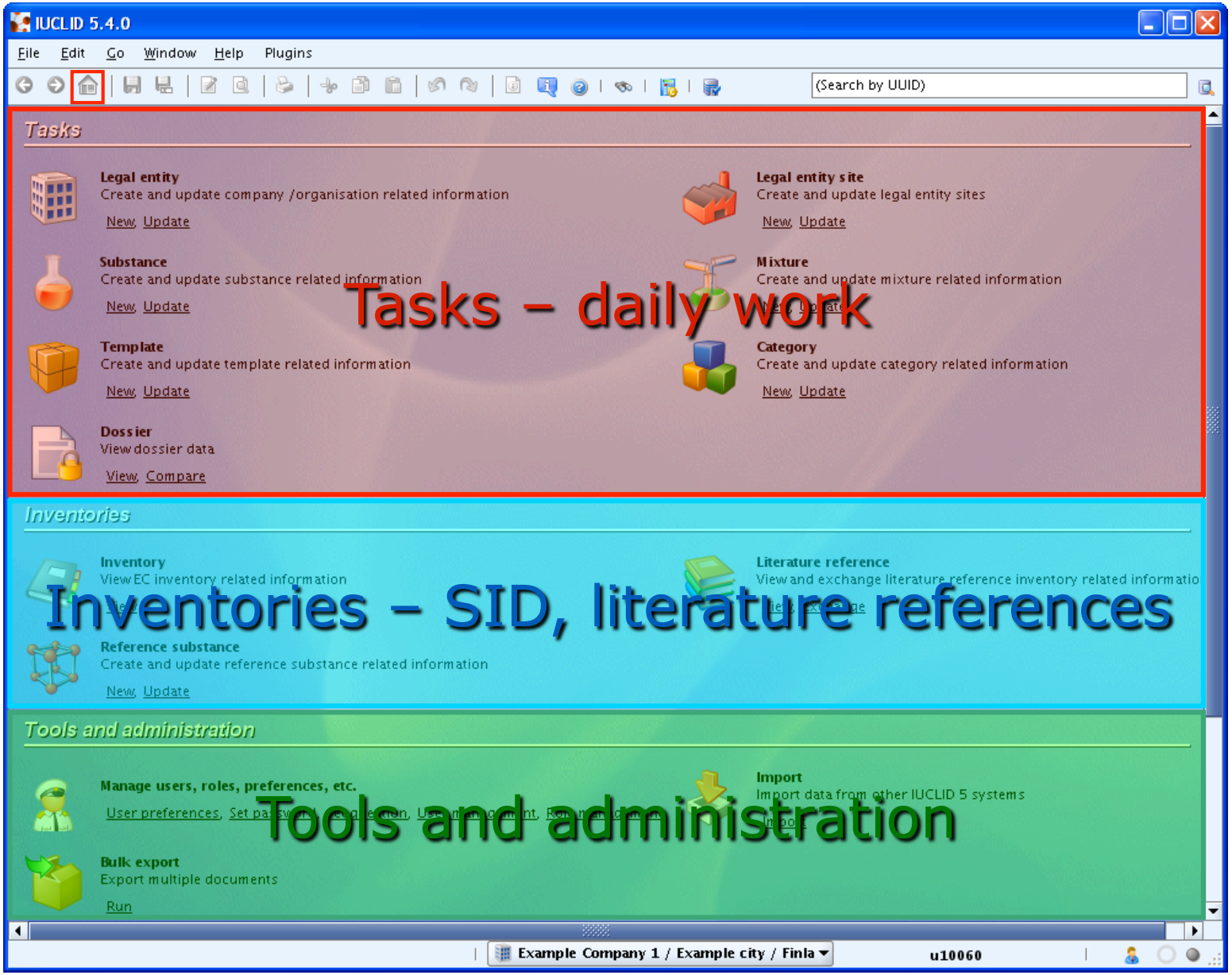
EC inventory and reference substances

- Download from the IUCLID website

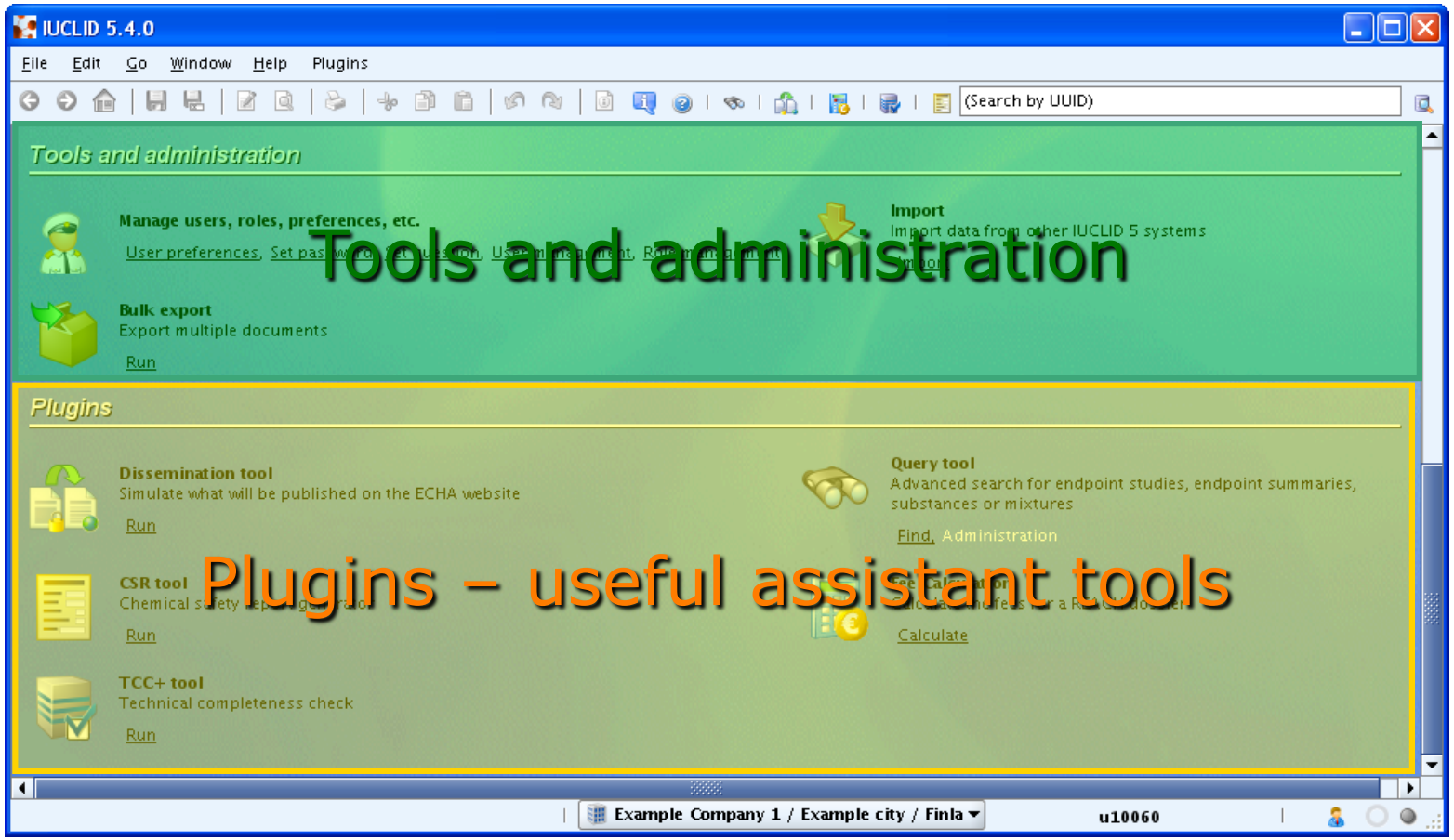


Structure and main elements of IUCLID 5

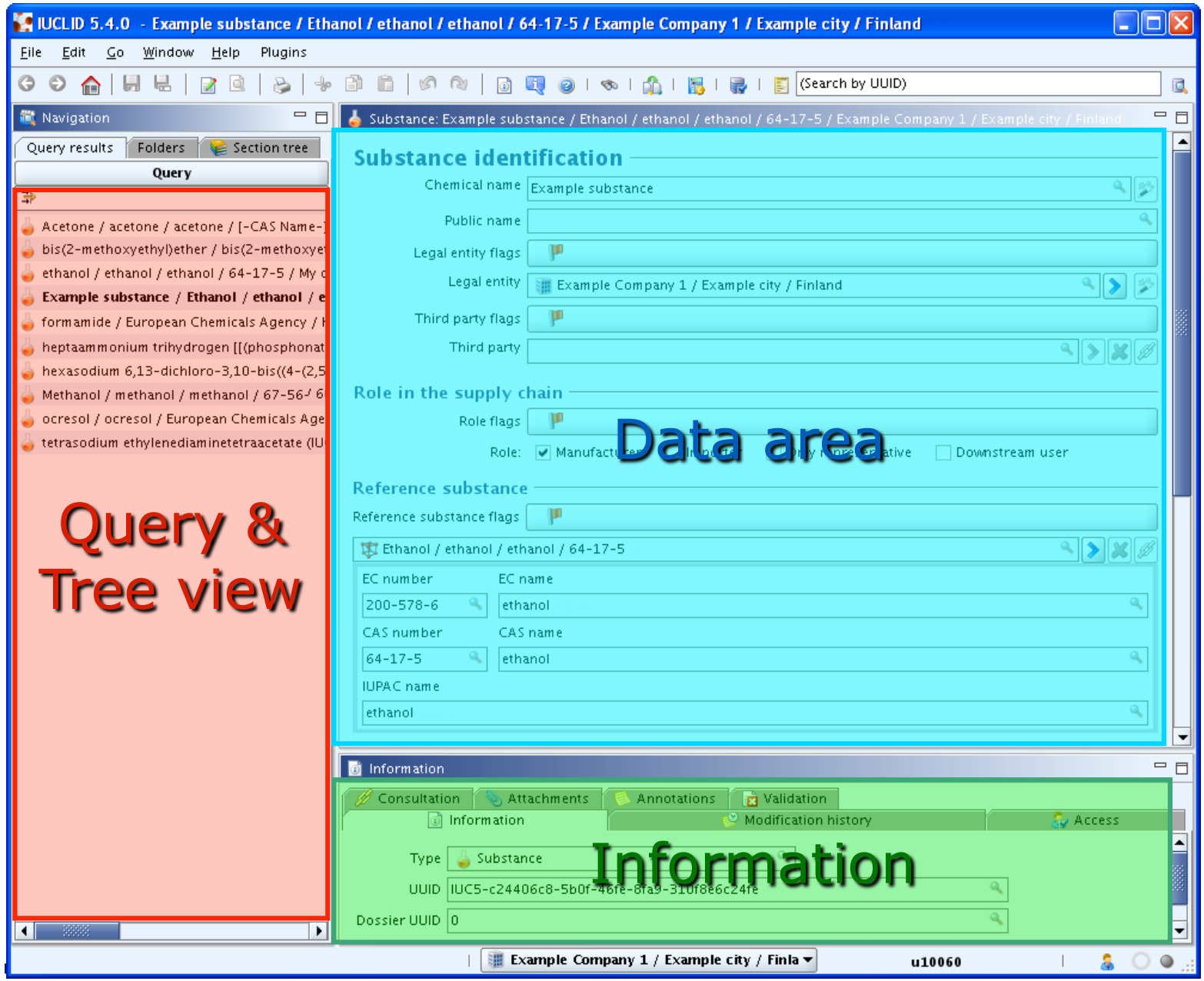
Structure of IUCLID 5



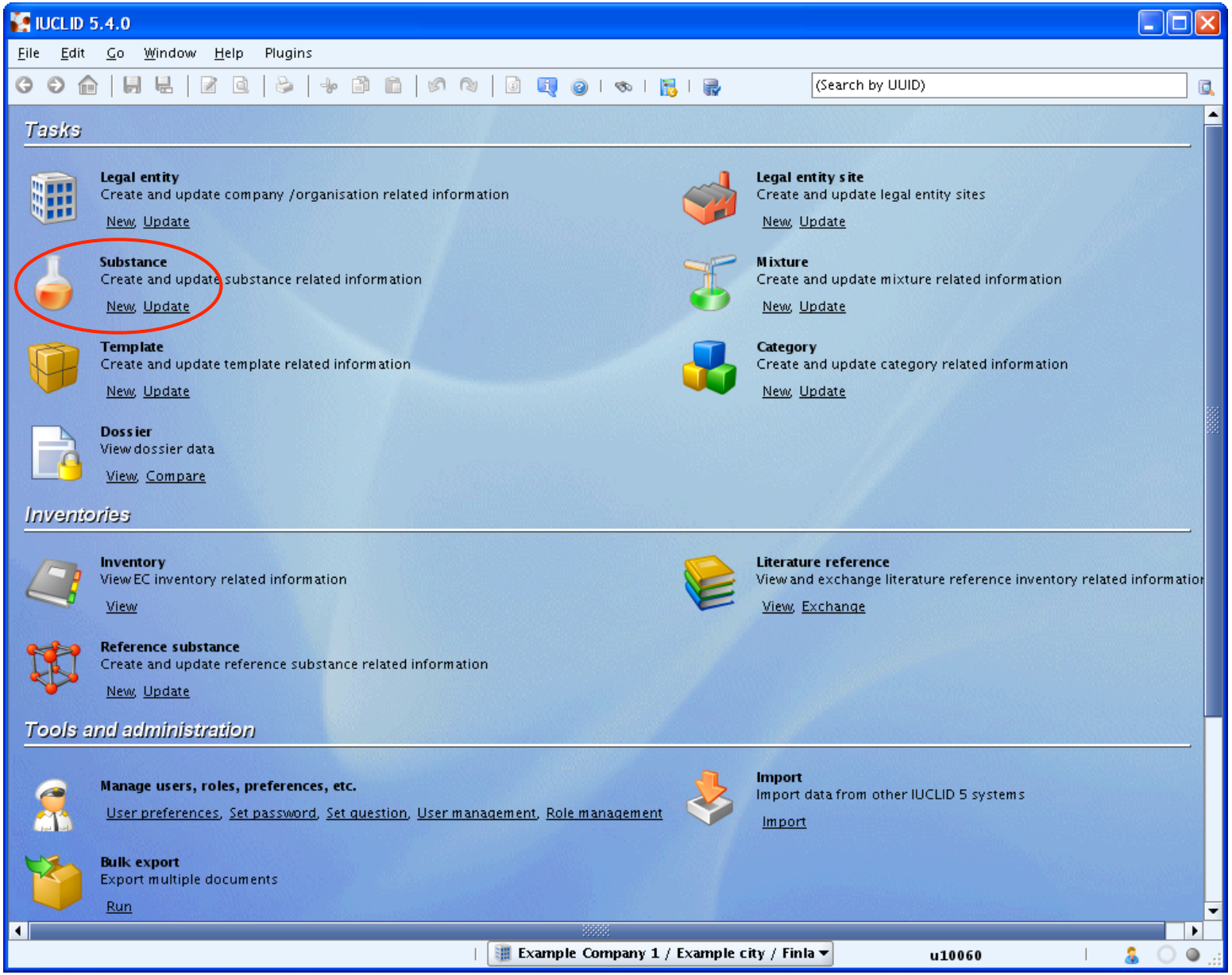
Structure of IUCLID 5



IUCLID structure



IUCLID Substance dataset



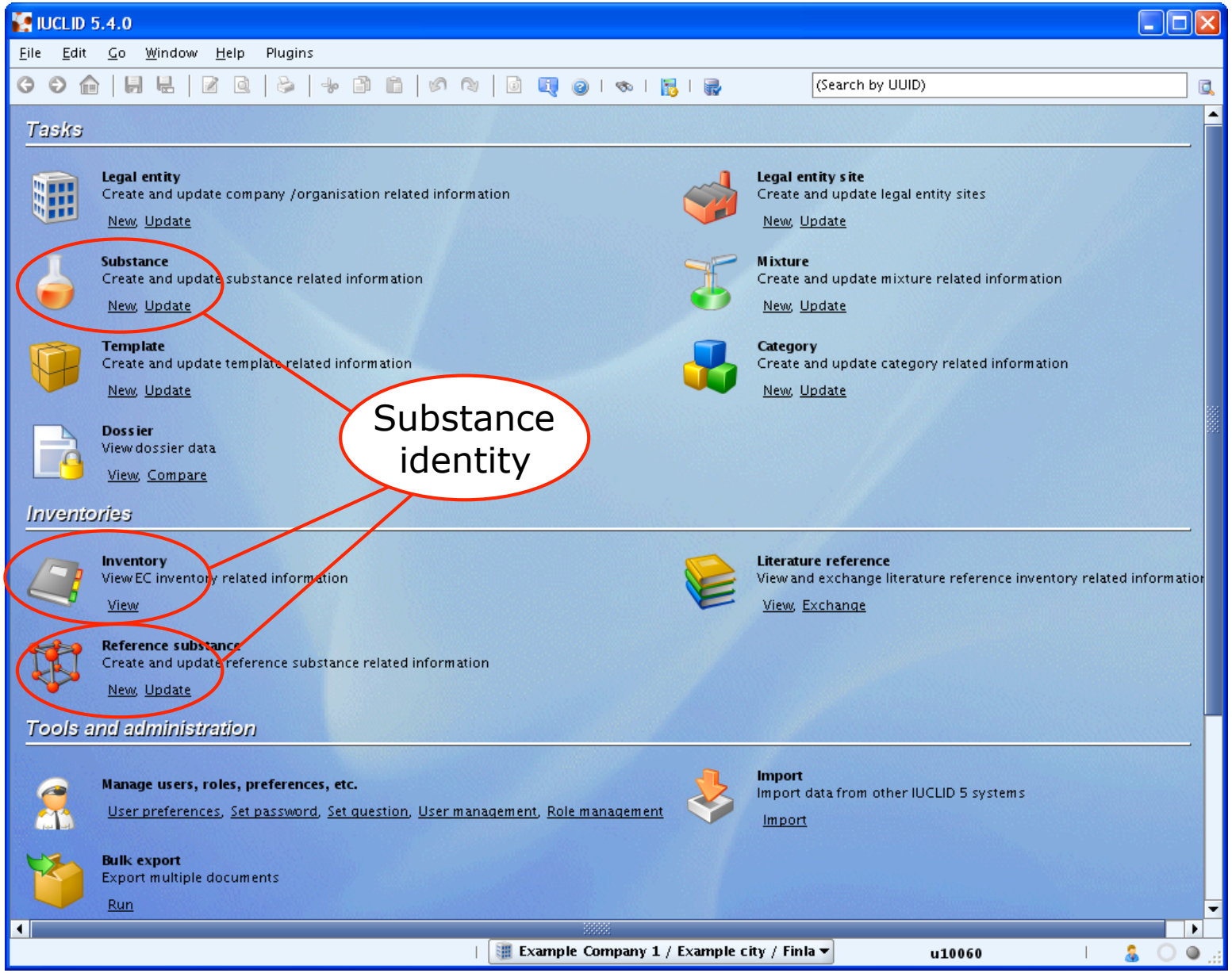
IUCLID Substance dataset

- The Substance dataset is the core of information in IUCLID;

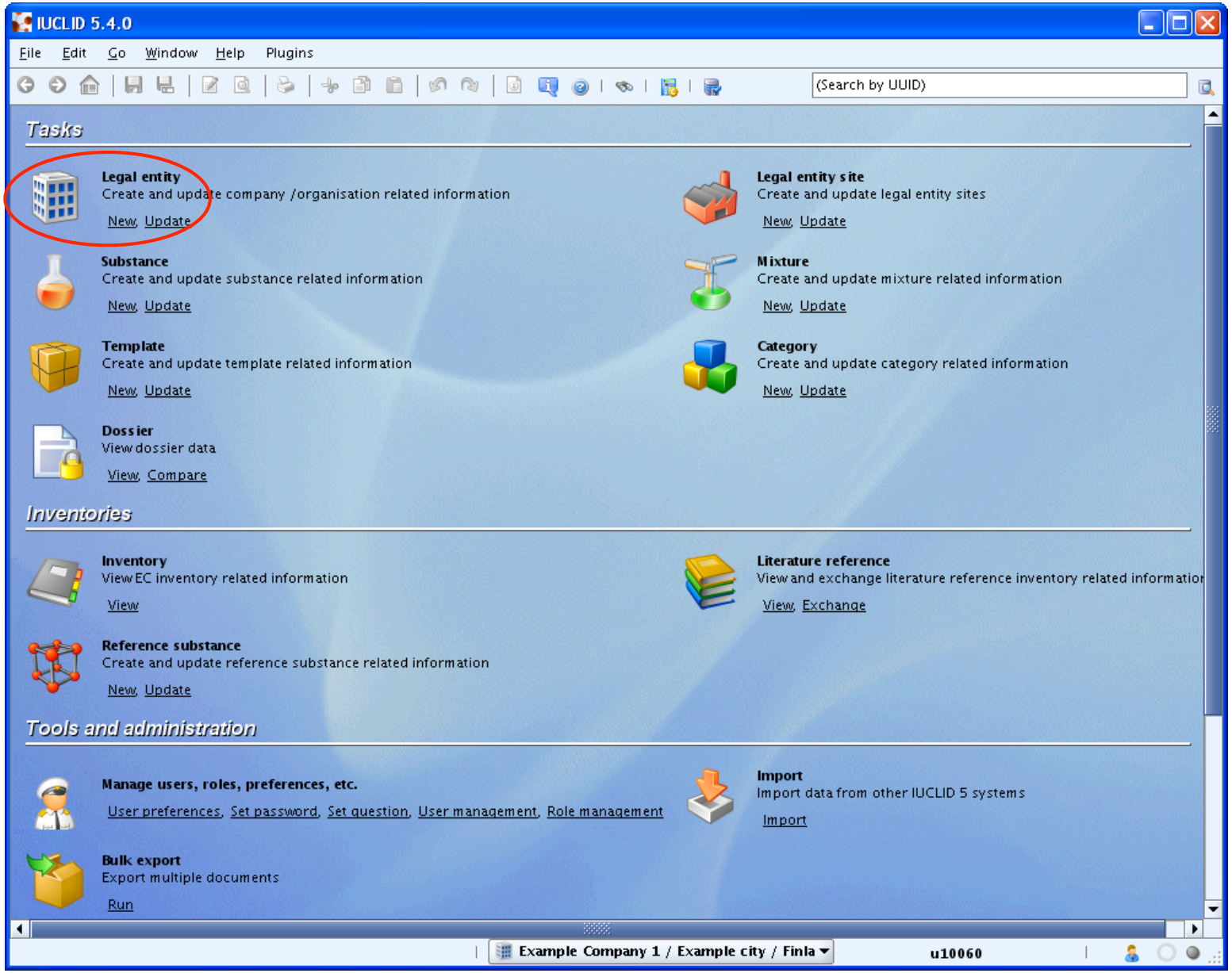
- Repository of data, which is used to create a Dossier for the substance to be registered;

- Contains all data related to a chemical substance:
  - chemical identity, including the substance composition
  - information on the classification and labelling
  - information on manufacture, use and exposure
  - all required and available (robust) study summaries
  - the Chemical Safety Report (if required)

Structure of IUCLID 5



IUCLID Legal entity



IUCLID Legal entity

- Each Substance dataset created in IUCLID is associated with one company/organisation – the Legal entity;
- The Legal entity object includes the name, the contact details, the contact person(s), and Legal entity specific identification numbers;
- The Legal entity information can be exchanged between applications using the LEOX file (Legal entity object XML file);

Legal entity – important!

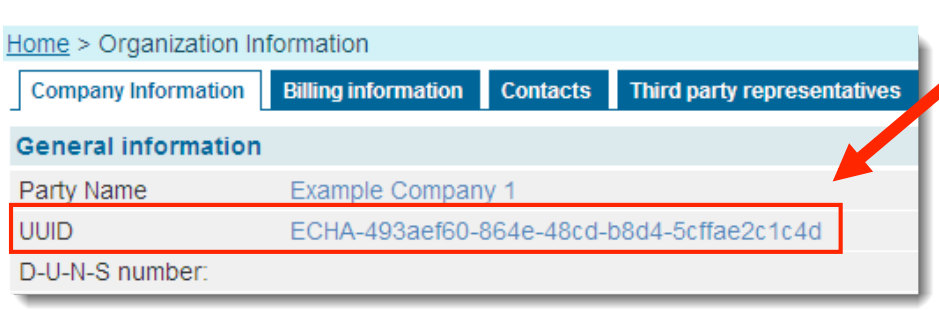
1. Only official LEO are valid: LEOX file downloaded from REACH-IT or IUCLID website

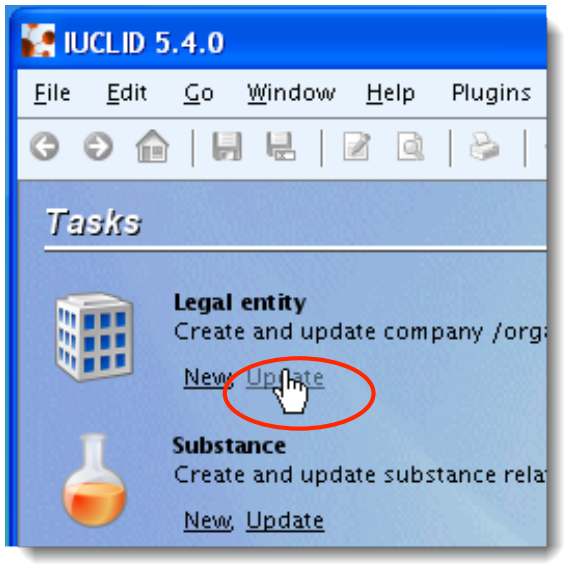
2. Important that the same LEOX is used in all contexts. LEO must be synchronised between REACH-IT – IUCLID.

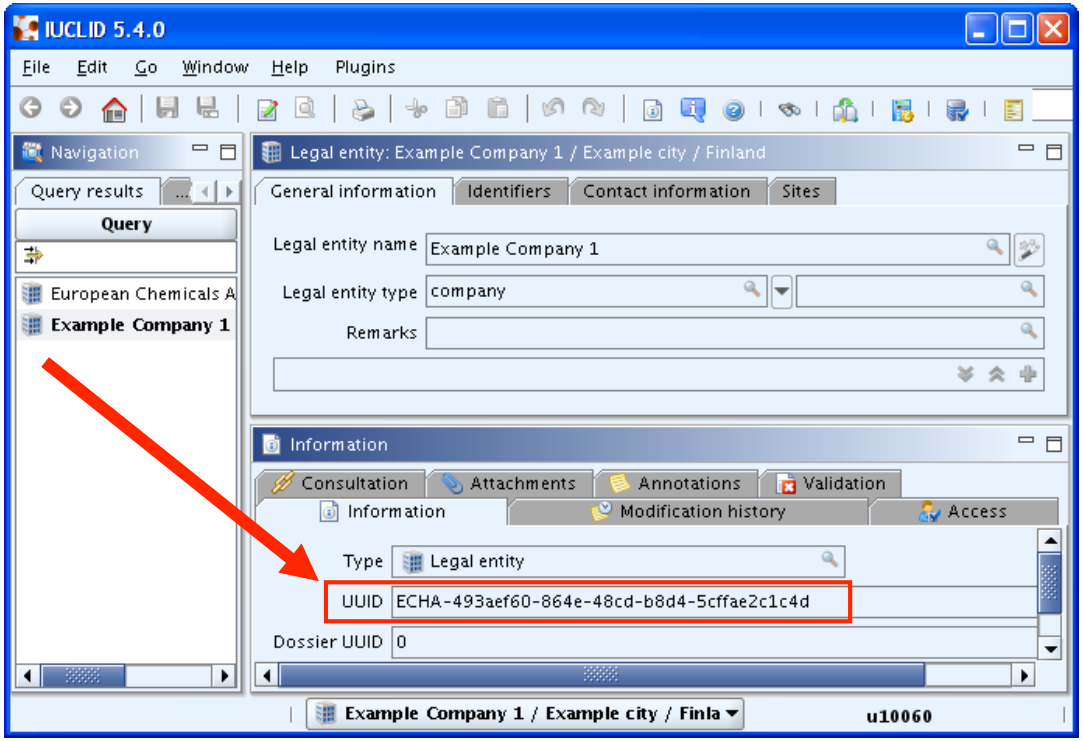
REACH-IT Industry User Manual 2

Data Submission Manual Part 4 - How to Pass Business Rule Verification ("Enforce Rules")

Synchronised Legal entity





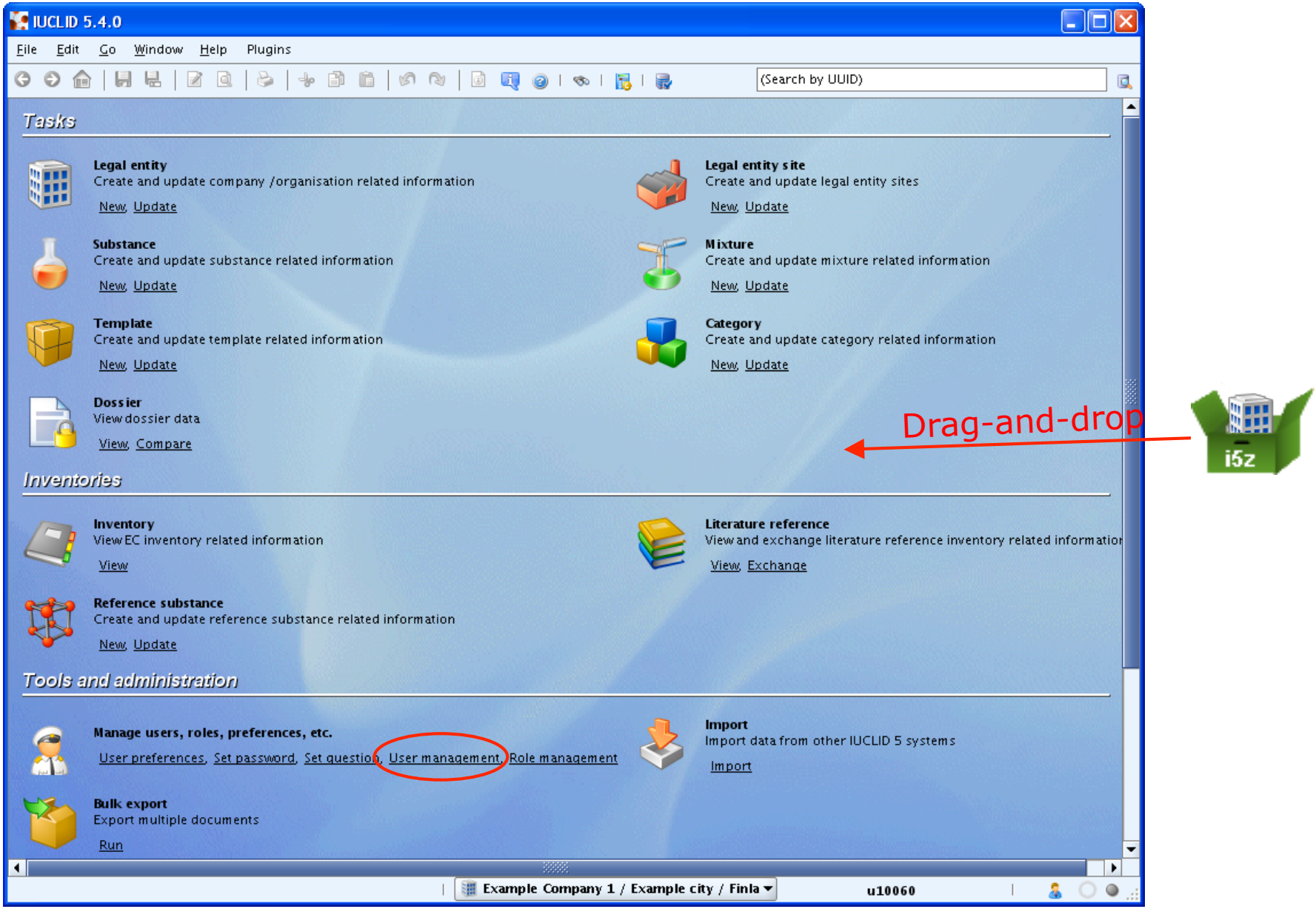


Official Legal entity

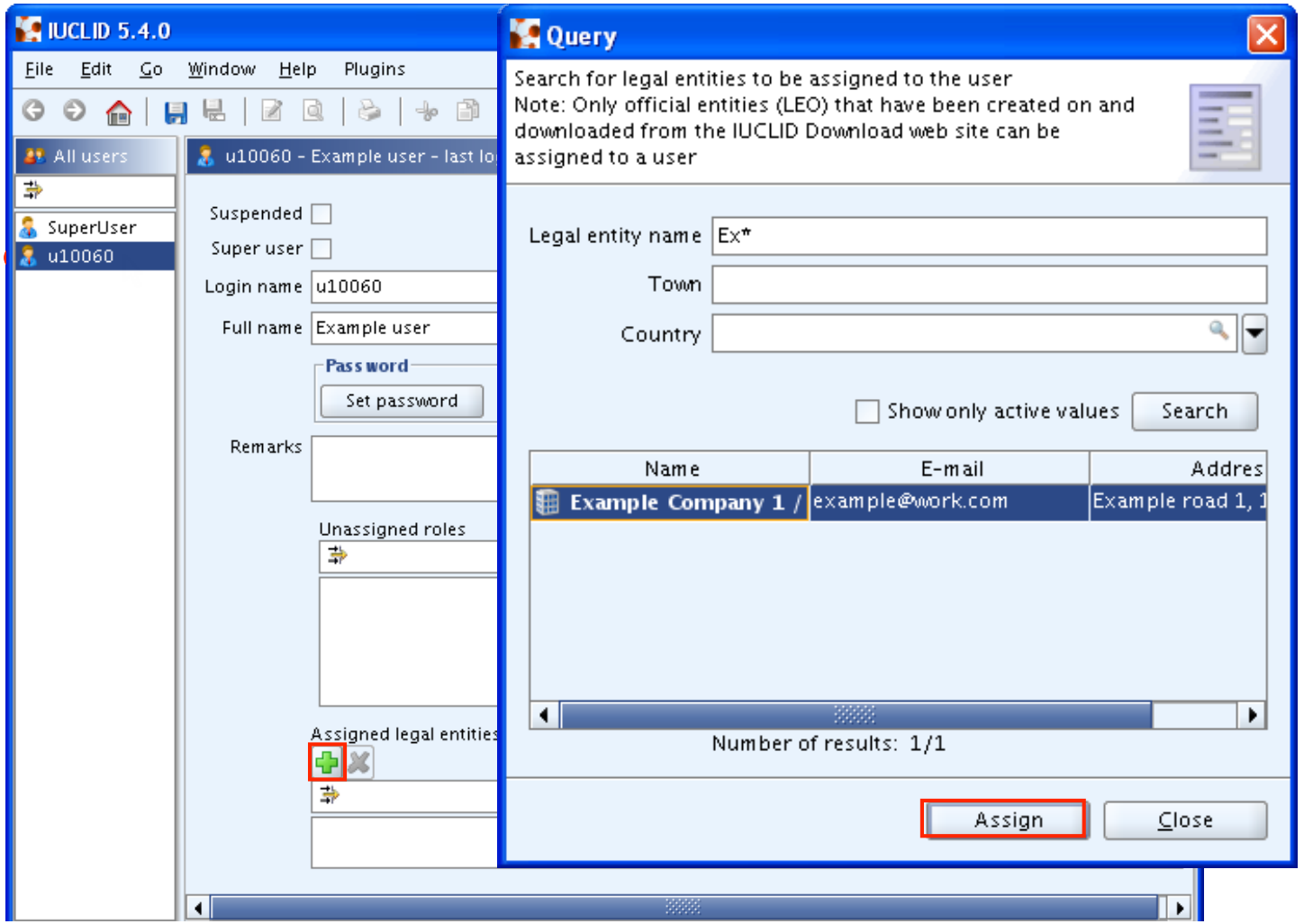
- REACH-IT:

<filename>.i5z

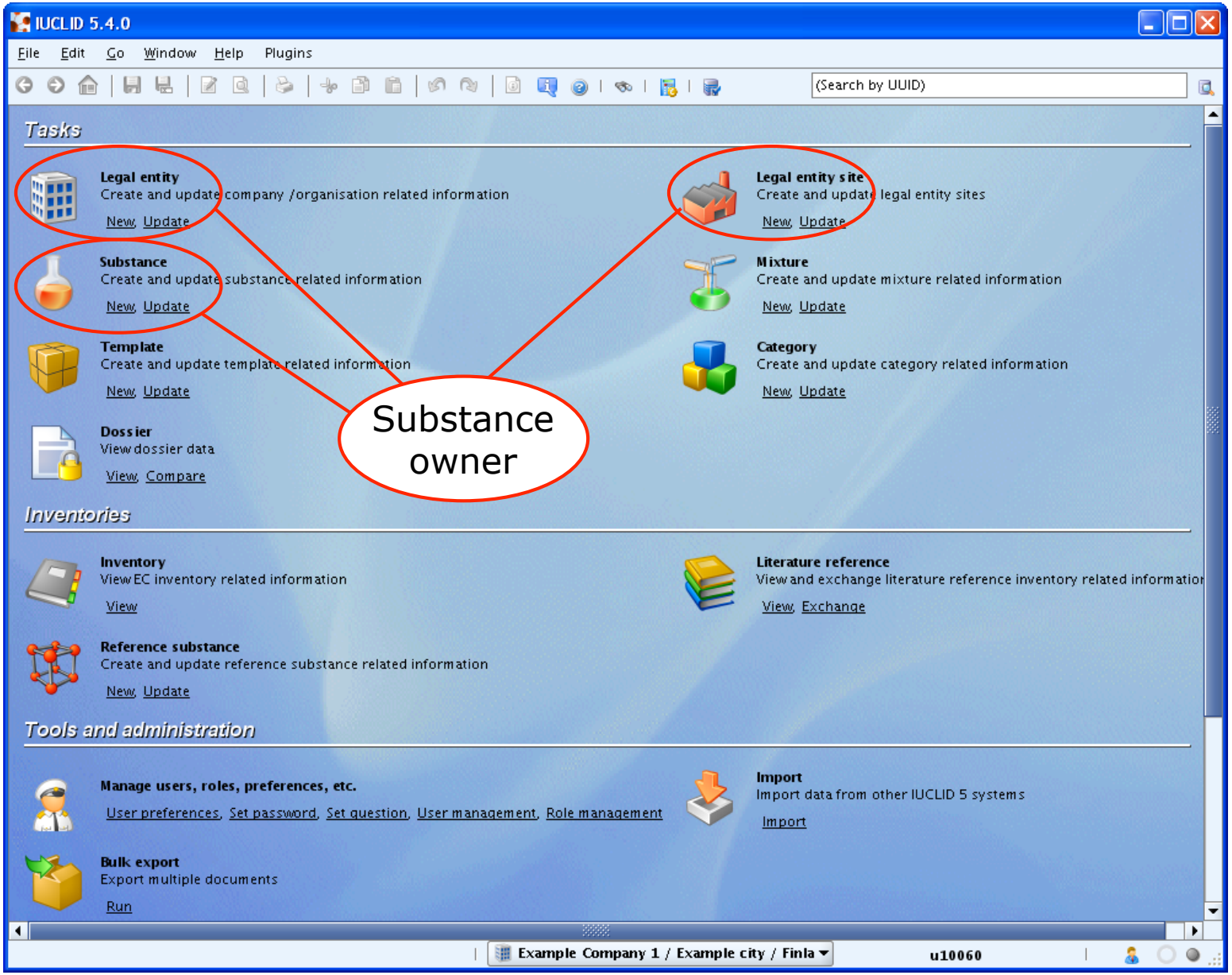
IUCLID Legal entity



IUCLID Legal entity



Structure of IUCLID 5



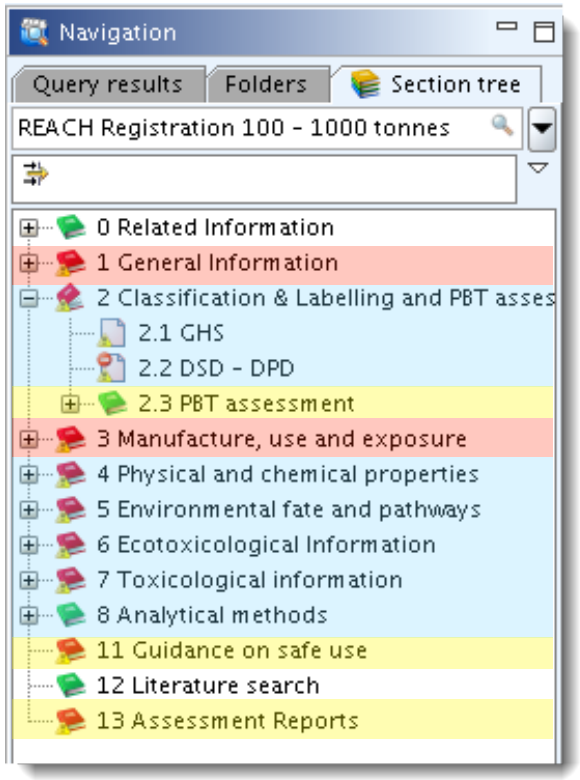
Filling in the substance dataset

Substance dataset – required information

- Own tonnage band(s) and JS tonnage band;
  - Highest information requirements must be covered

- Information requirements
  - REACH Articles 10–12 (standard), 17–19 (intermediates)
  - REACH Annex VI
  - REACH Annexes VII – X (tonnage dependent)
  - REACH Article 14 and Annex I (CSR)

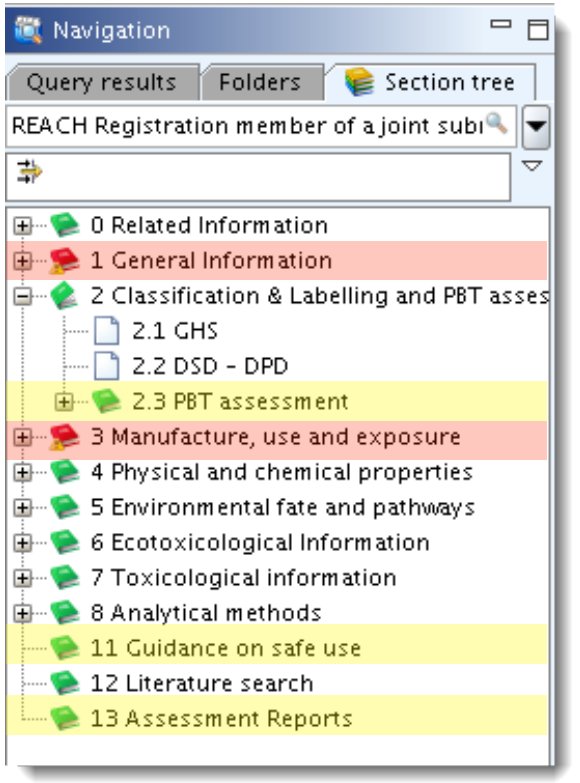
Substance dataset – Joint Submission



Information submitted by each registrant in their own dossier.

Information submitted only by the LEAD registrant on behalf of the JS (unless member registrant opts out).

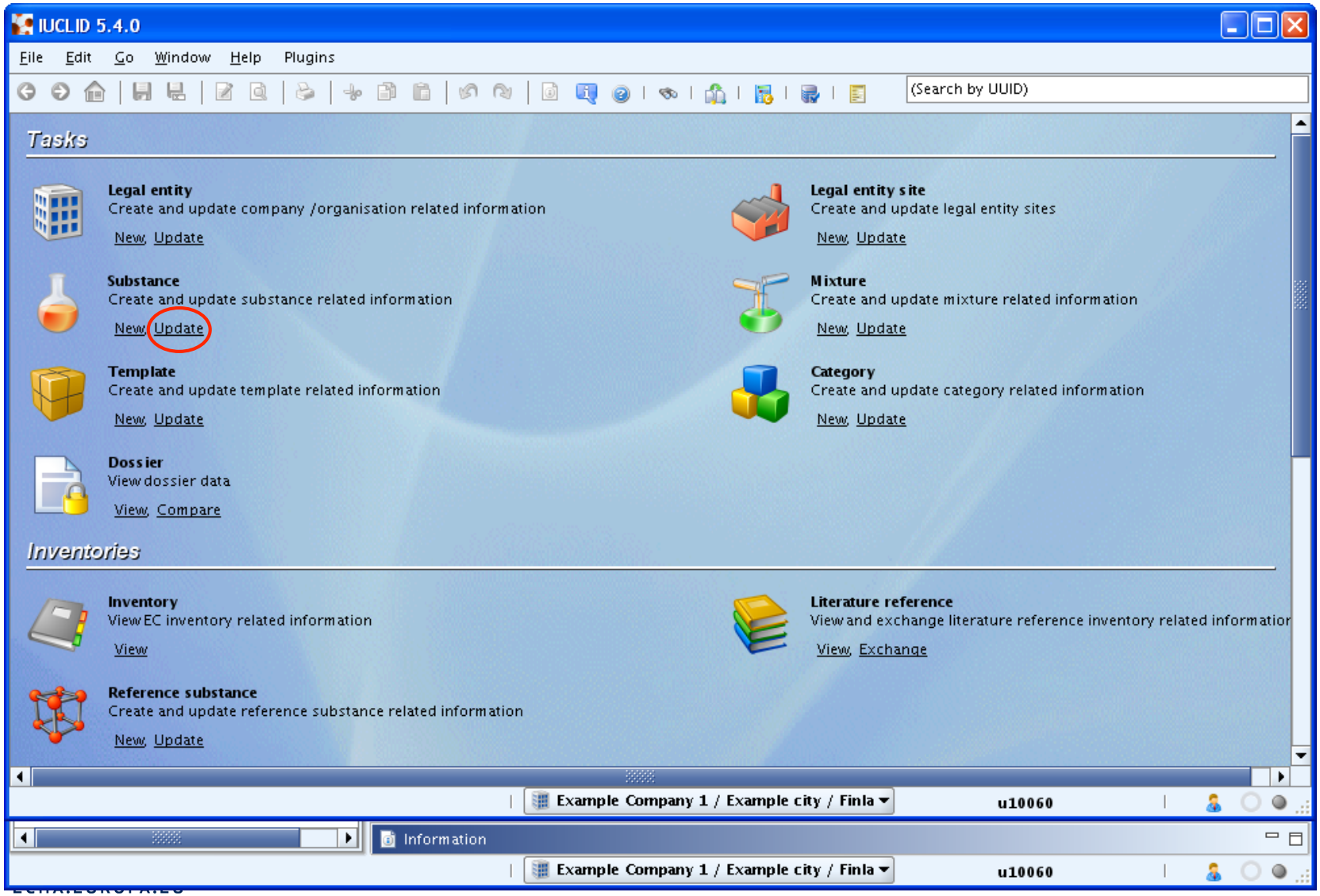
Information submitted by the LEAD on behalf of the JS, or individually by each registrant, according to agreement.



How to fill in a Substance dataset

- Creation of a new Substance dataset
- Sections 1.1 and 1.2
  - Linking of a reference substance
- Section 3.5 on Life Cycle description
  - Use reporting by JS Lead
- Sections 4 – 7
  - How to create an endpoint study record
- Section 13
  - How to attach a Chemical Safety Report

Creation of a new Substance dataset



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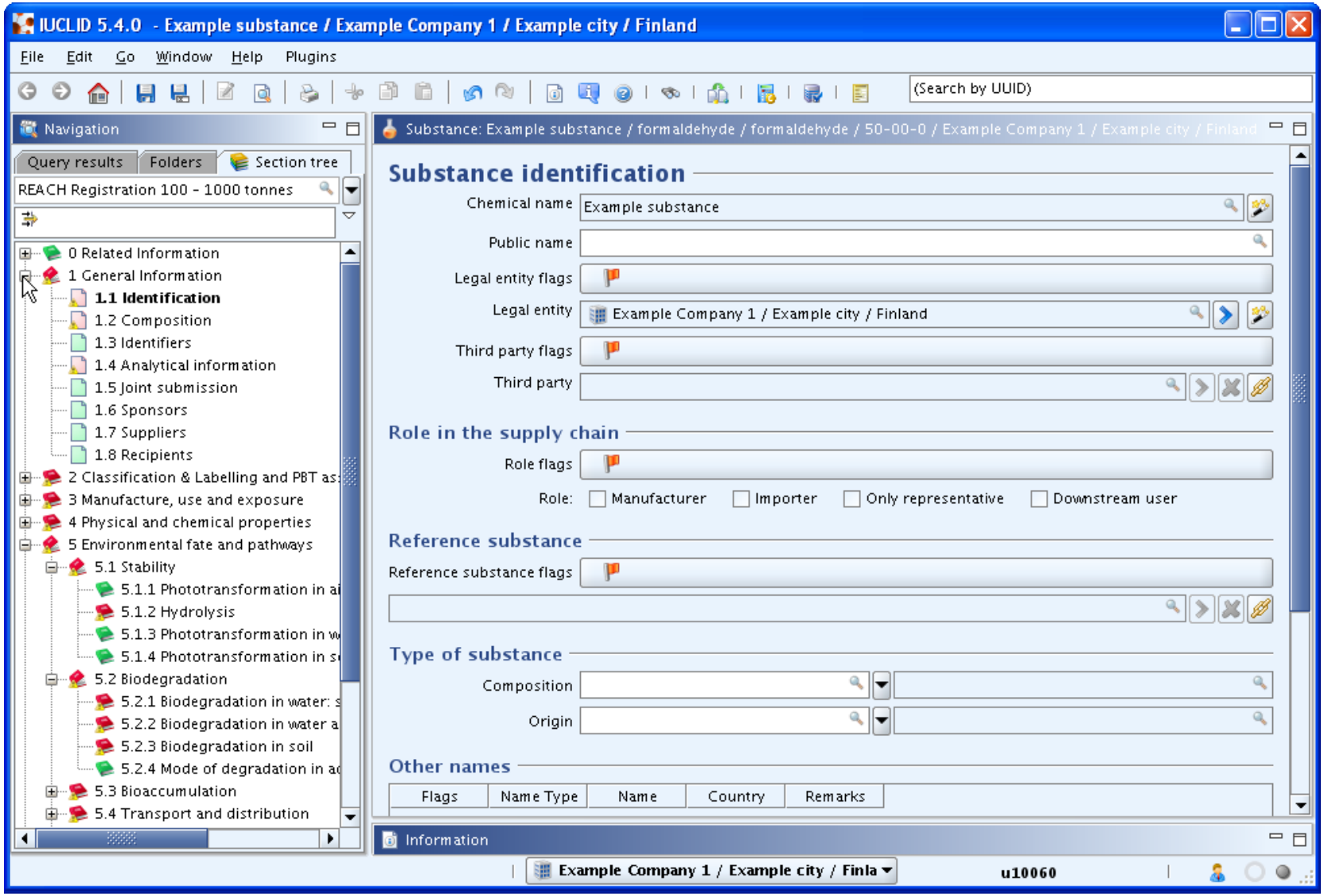

How to fill in a Substance dataset

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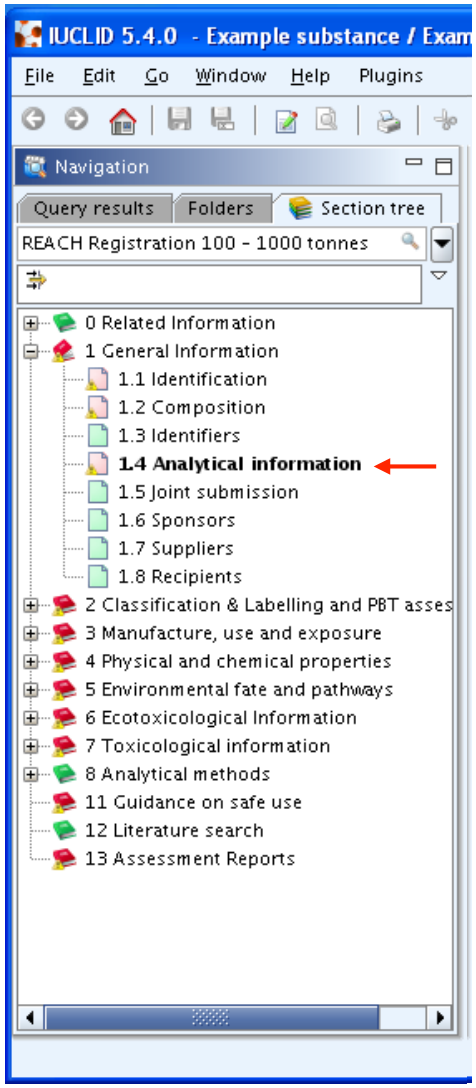
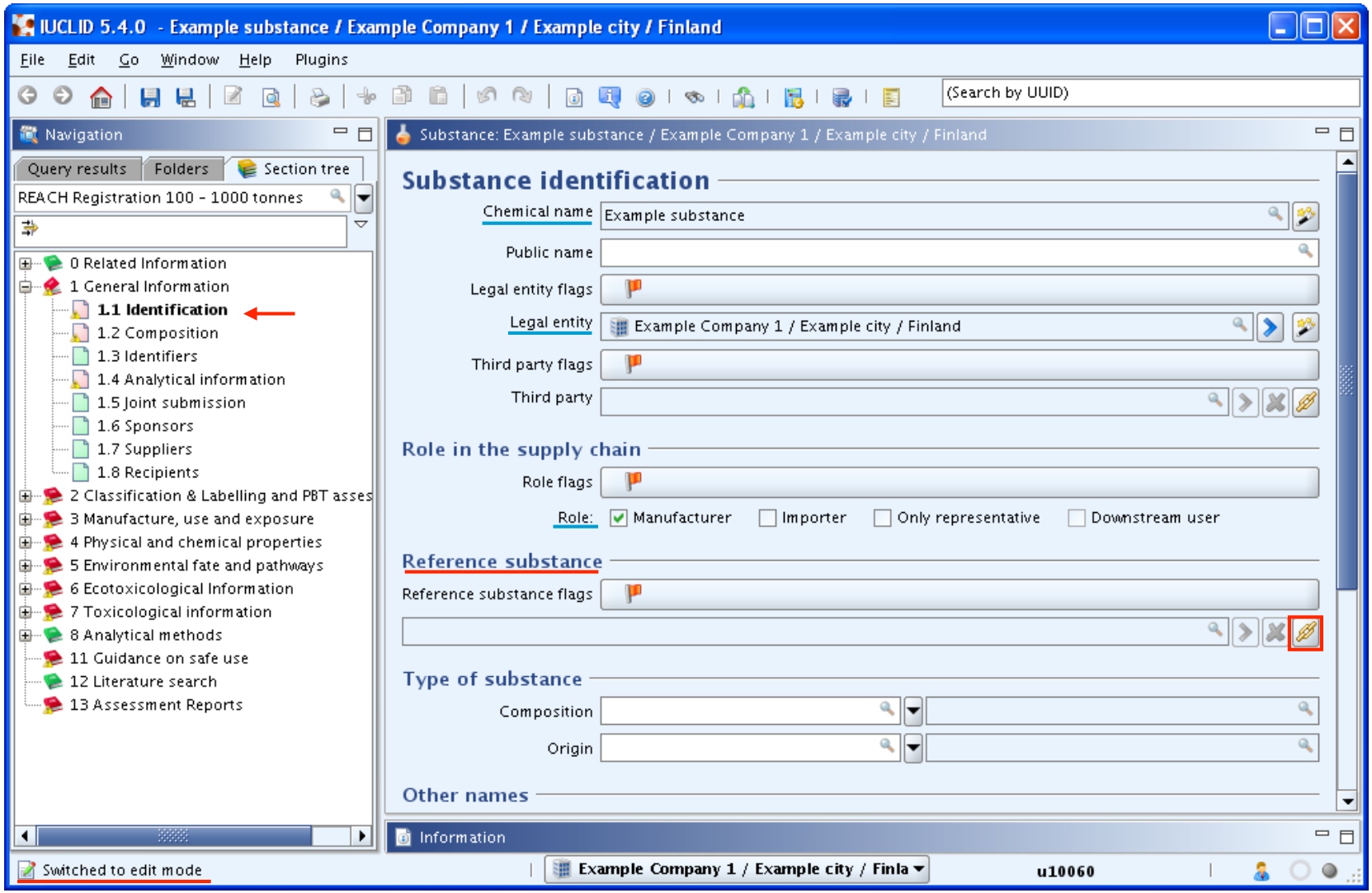
Sections 1.1 and 1.2 – Reference substance



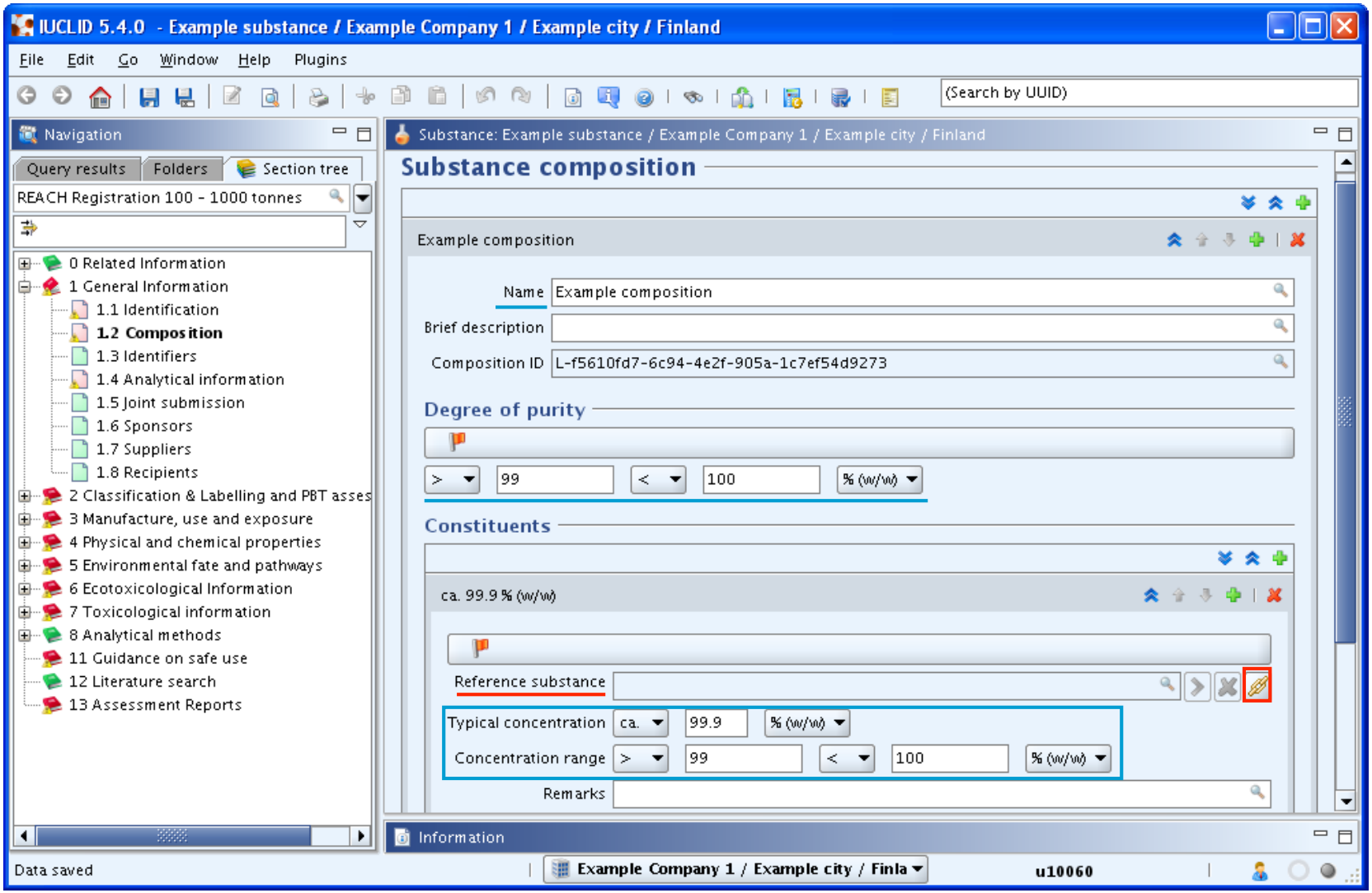
Data Submission Manual Part 18 - How to report the substance identity in IUCLID 5 for registration under REACH

Guidance for identification and naming of substances under REACH and CLP

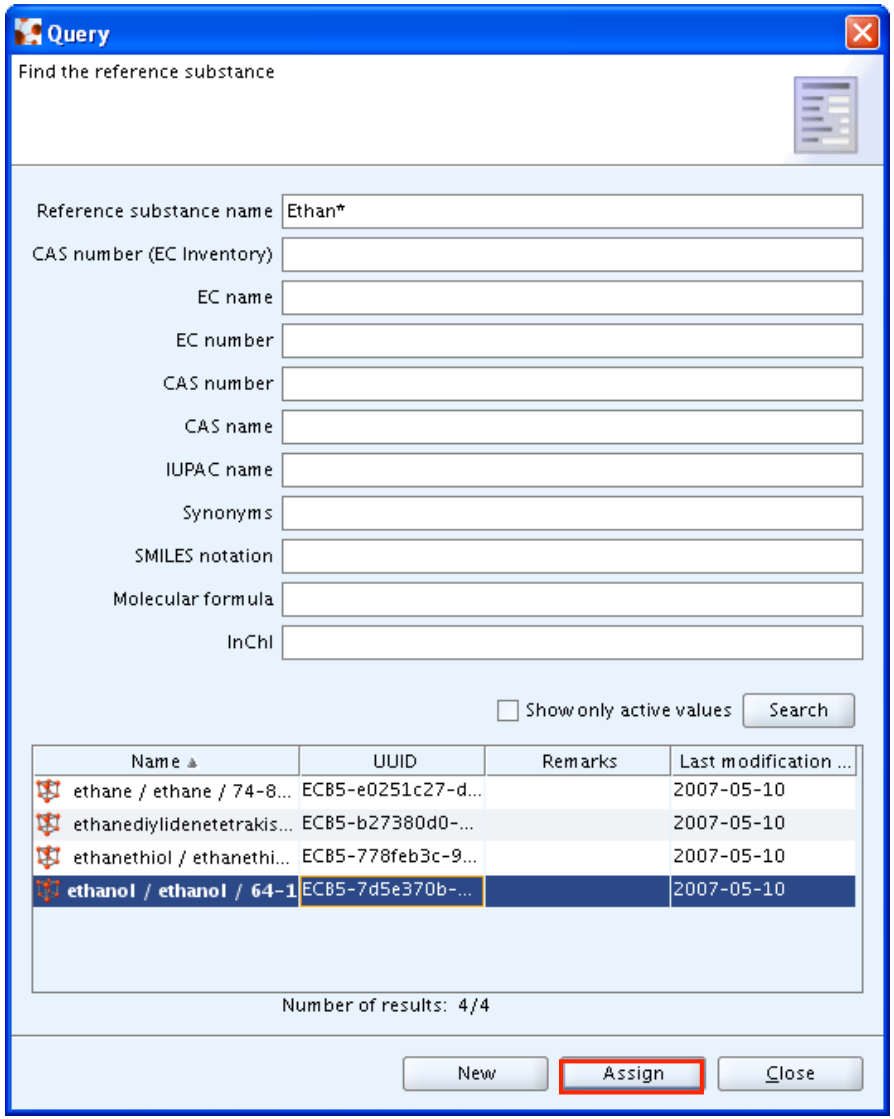
Sections 1.1 and 1.2 – Reference substance



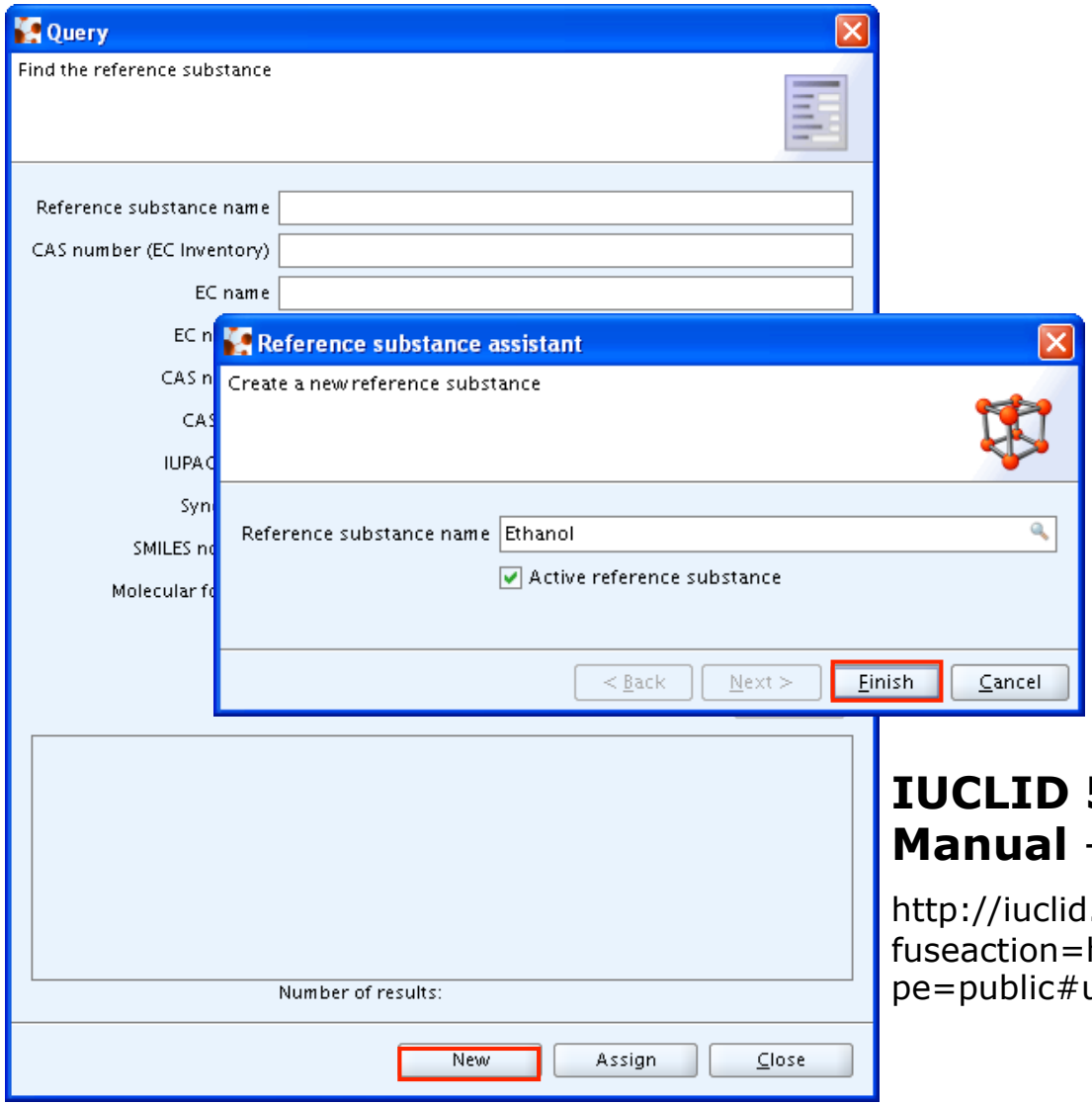
Sections 1.1 and 1.2 – Reference substance



Linking an existing Reference substance

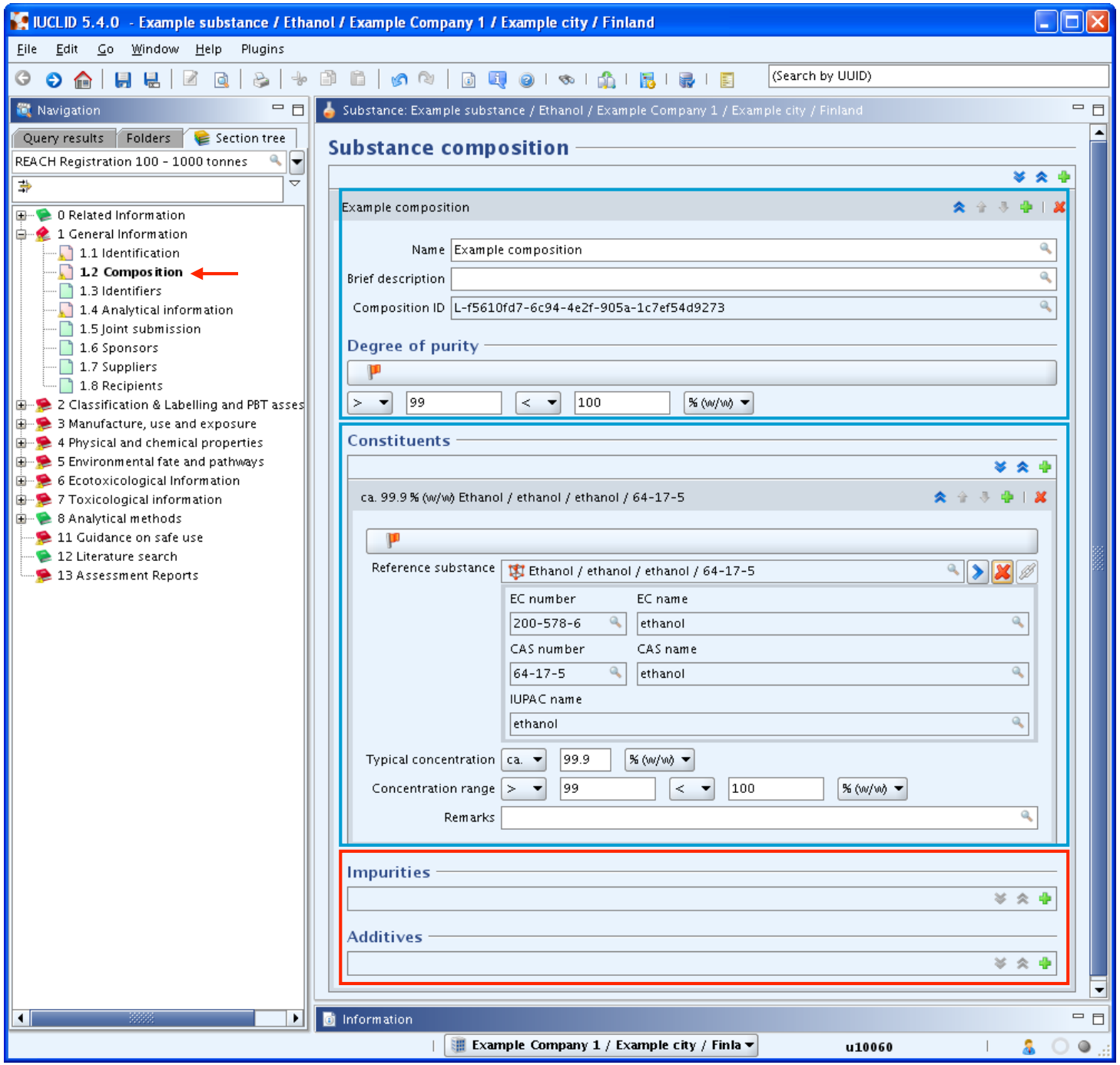


Creating a new Reference substance



IUCLID 5 Getting Started Manual – chapter 3

http://iuclid.eu/index.php?fuseaction=home.documentation&type=public#usermanual


IUCLID 5.4.0 - Example substance / Ethanol / Example Company 1 / Example city / Finland
File Edit Go Window Help Plugins
(Search by UUID)
Navigation
Query results Folders Section tree
REACH Registration 100 - 1000 tonnes
0 Related Information
1 General Information
1.1 Identification
1.2 Composition
1.3 Identifiers
1.4 Analytical information
1.5 Joint submission
1.6 Sponsors
1.7 Suppliers
1.8 Recipients
2 Classification & Labelling and PBT asses
3 Manufacture, use and exposure
4 Physical and chemical properties
5 Environmental fate and pathways
6 Ecotoxicological Information
7 Toxicological information
8 Analytical methods
11 Guidance on safe use
12 Literature search
13 Assessment Reports
Substance: Example substance / Ethanol / Example Company 1 / Example city / Finland
Substance composition
Example composition
Name Example composition
Brief description
Composition ID L-f5610fd7-6c94-4e2f-905a-1c7ef54d9273
Degree of purity
> 99 < 100 % (w/w)
Constituents
ca. 99.9 % (w/w) Ethanol / ethanol / ethanol / 64-17-5
Reference substance Ethanol / ethanol / ethanol / 64-17-5
EC number 200-578-6
EC name ethanol
CAS number 64-17-5
CAS name ethanol
IUPAC name ethanol
Typical concentration ca. 99.9 % (w/w)
Concentration range > 99 < 100 % (w/w)
Remarks
Impurities
Additives
Information
Example Company 1 / Example city / Finla
u10060

How to fill in a Substance dataset

- Creation of a new Substance dataset
- Sections 1.1 and 1.2
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  - **Use reporting by JS Lead**
- Sections 4 – 7
  - How to create an endpoint study record
- Section 13
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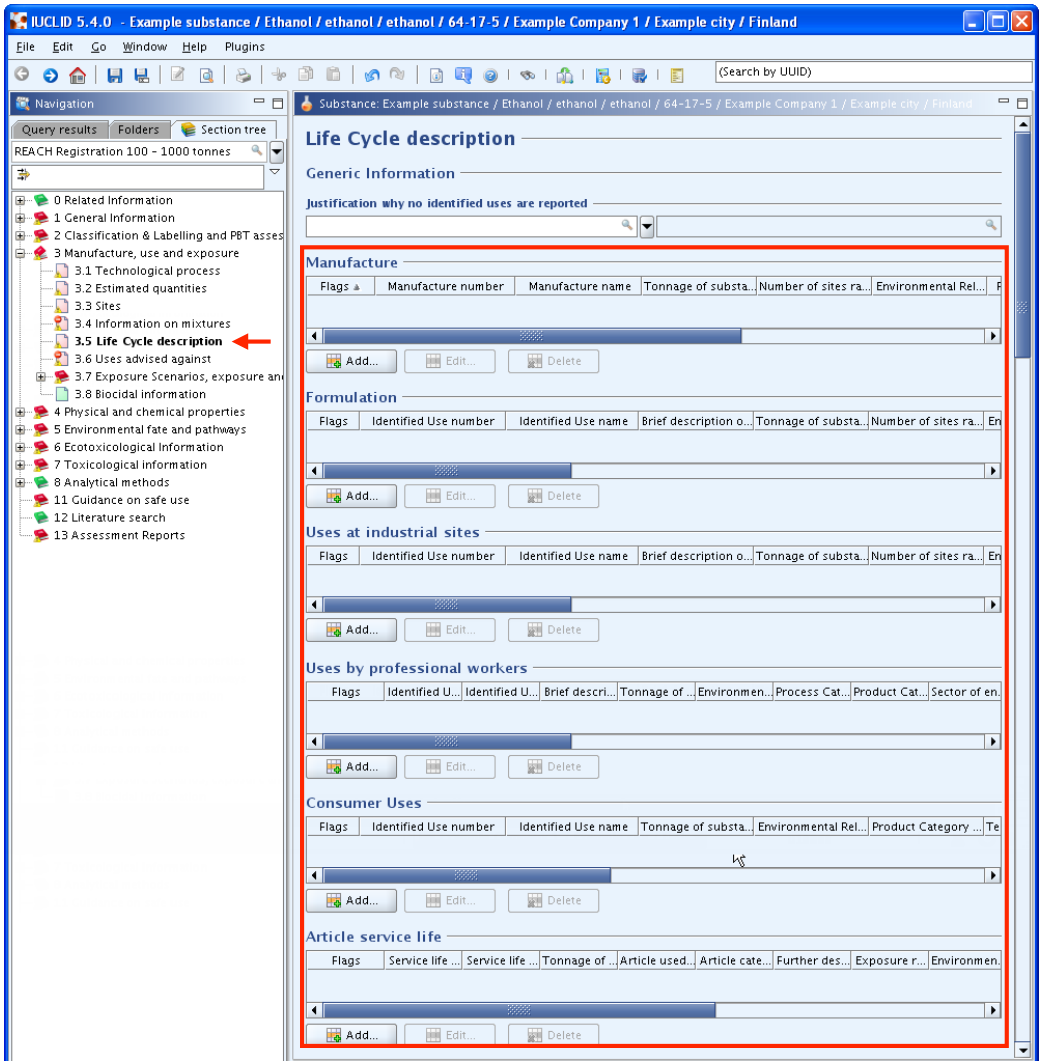
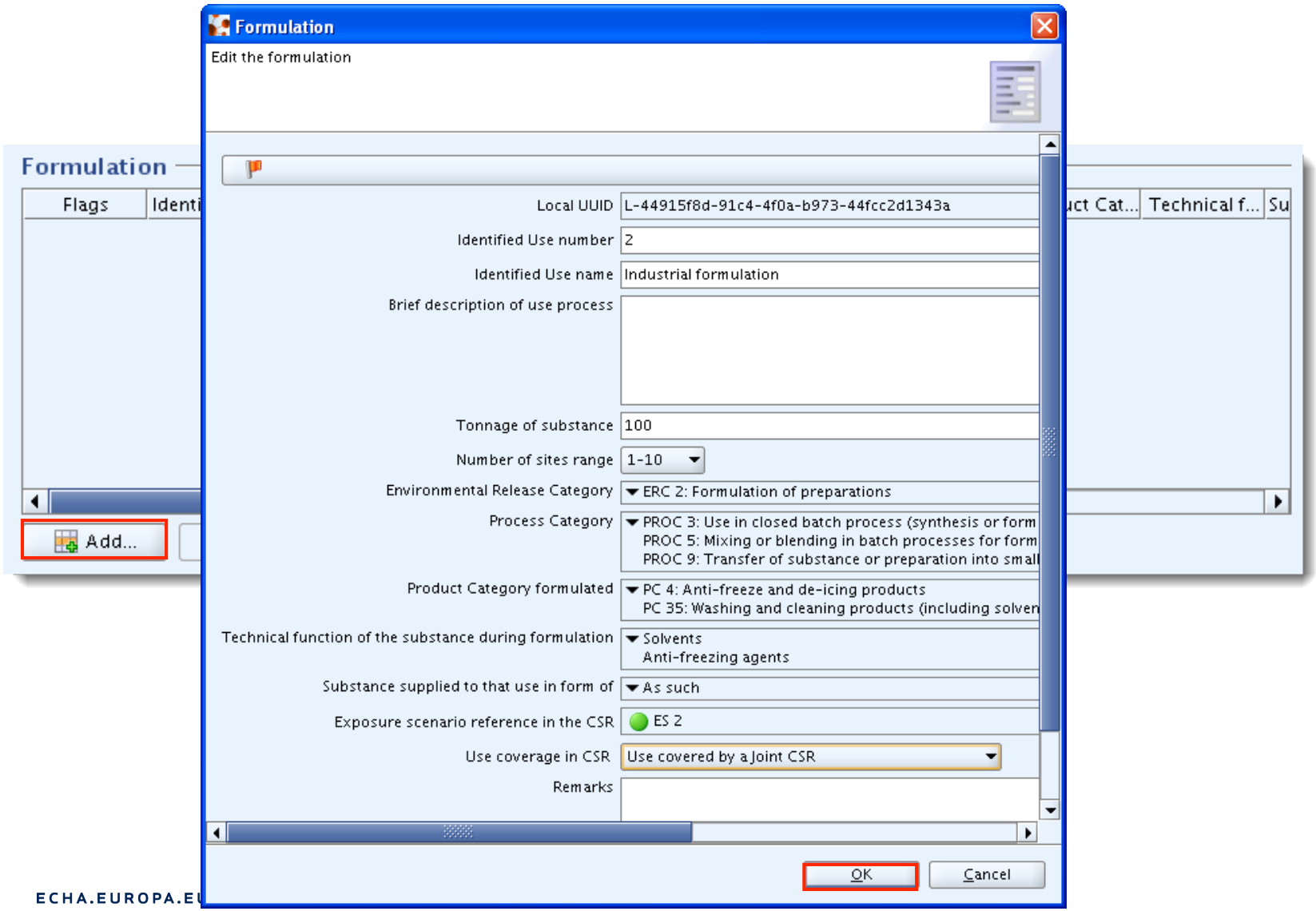
Section 3.5 – use reporting by JS Lead



Section 3.5 – use reporting by JS Lead

- Each registrant reports their own uses in section 3.5;
- JS leads may in addition to their own uses report uses by members if they are included in the joint Chemical Safety Report;
- IUCLID 5.4 contains field 'Use coverage in CSR' in each of the tables in section 3.5;
  - Not mandatory field, but highly recommended!
- Guidance on information requirements and chemical safety assessment Chapter R.12: Use descriptor system

Section 3.5 – use reporting by JS Lead



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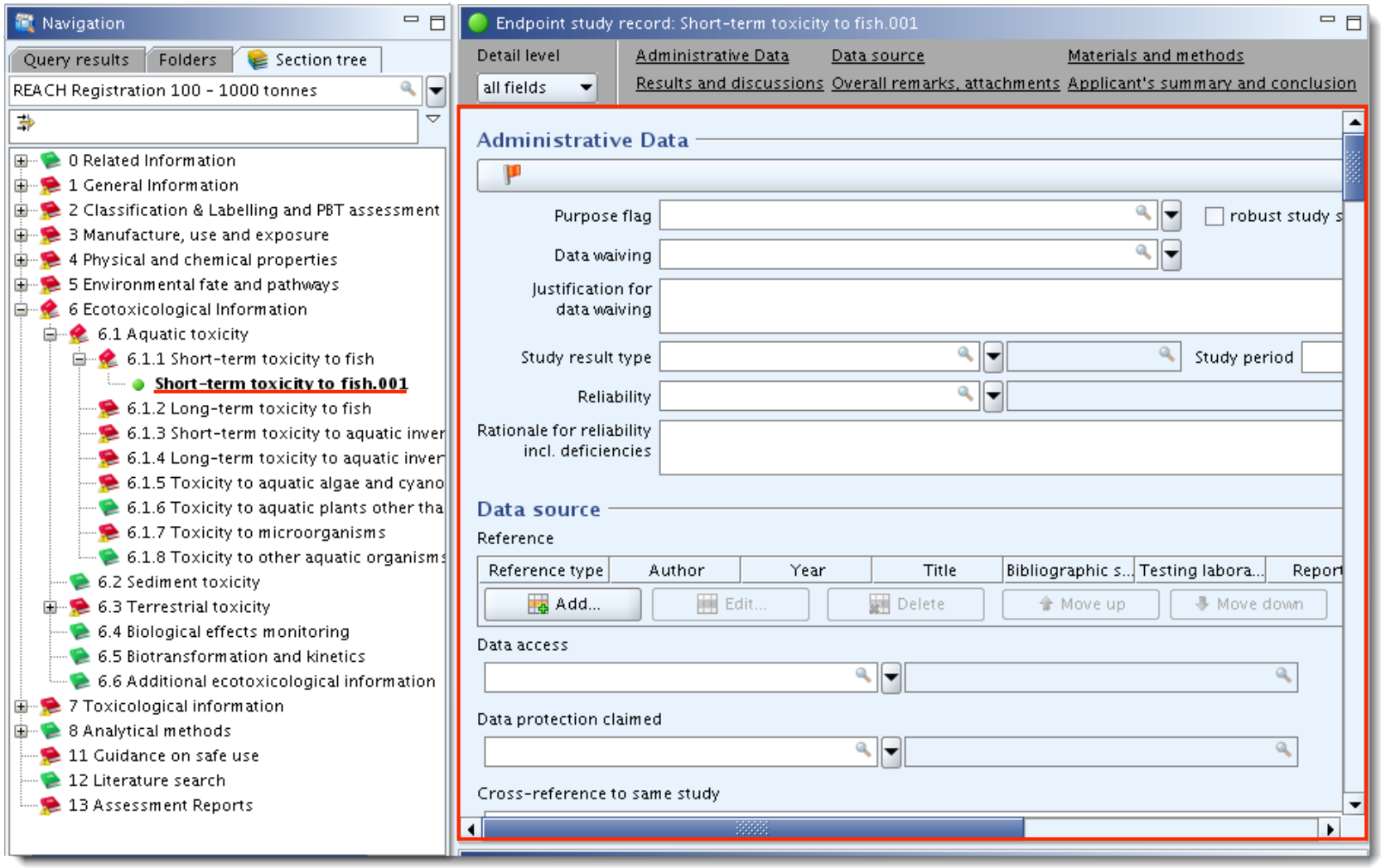
- Section 13
  - How to attach a Chemical Safety Report

Creation of endpoint study records

- IUCLID sections 4–13 are structurally different from sections 0–3;
- In a new Substance dataset these sections contain no data fields: endpoint study records must be created by right-clicking on section symbol;
- Several endpoint study records, and one endpoint summary can be created in each section.

Creation of endpoint study records



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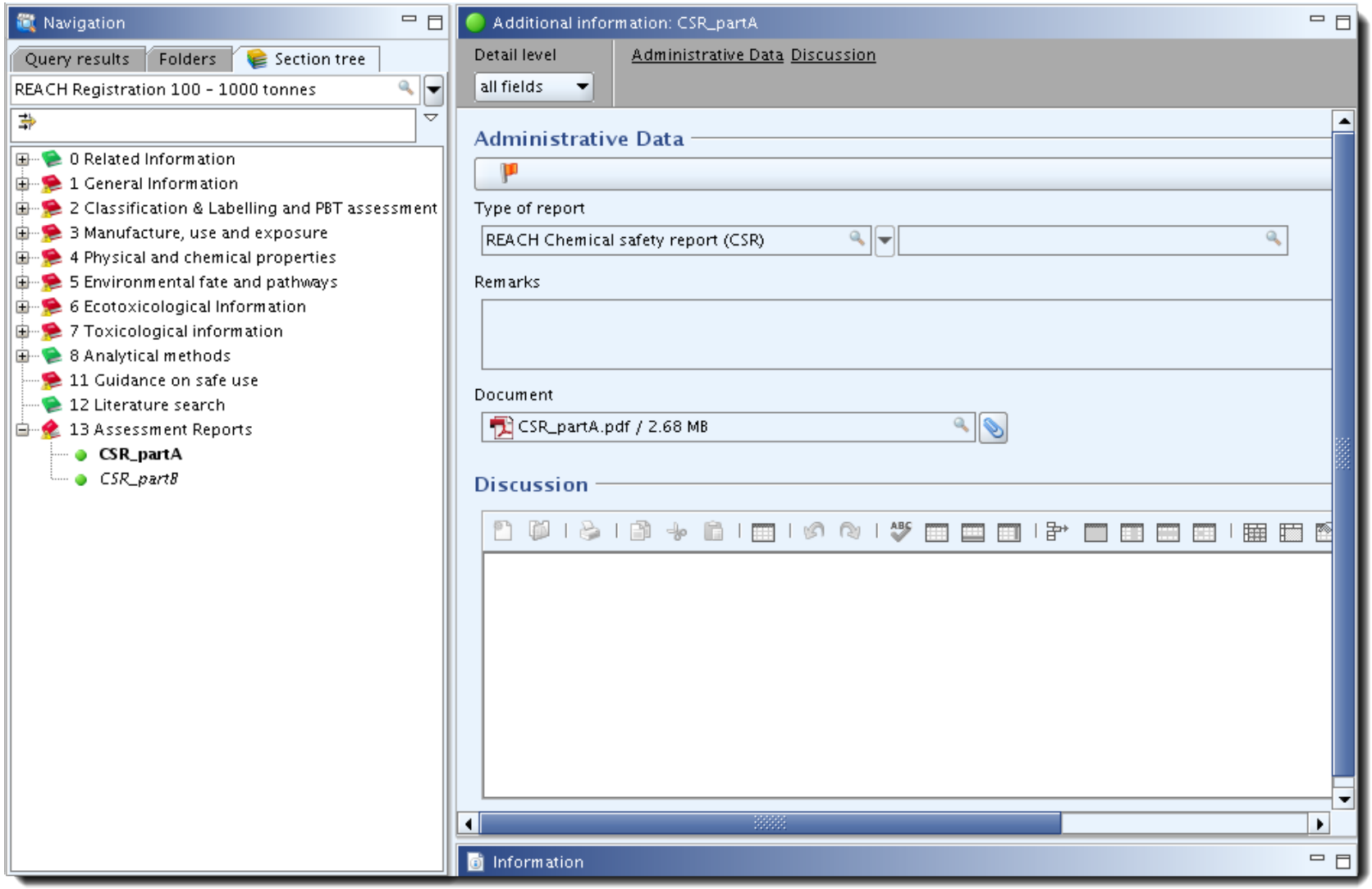
  - **How to attach a Chemical Safety Report**

Section 13 – how to attach a CSR



Creating and exporting a dossier

How to:

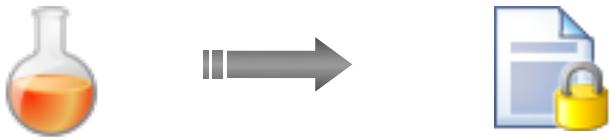
- Create a dossier
- Run the TCC plug-in on the dossier
- Export the dossier

Creation of a JS lead IUCLID dossier

- Starting point is a complete Substance dataset;
  - all information required for JS tonnage band

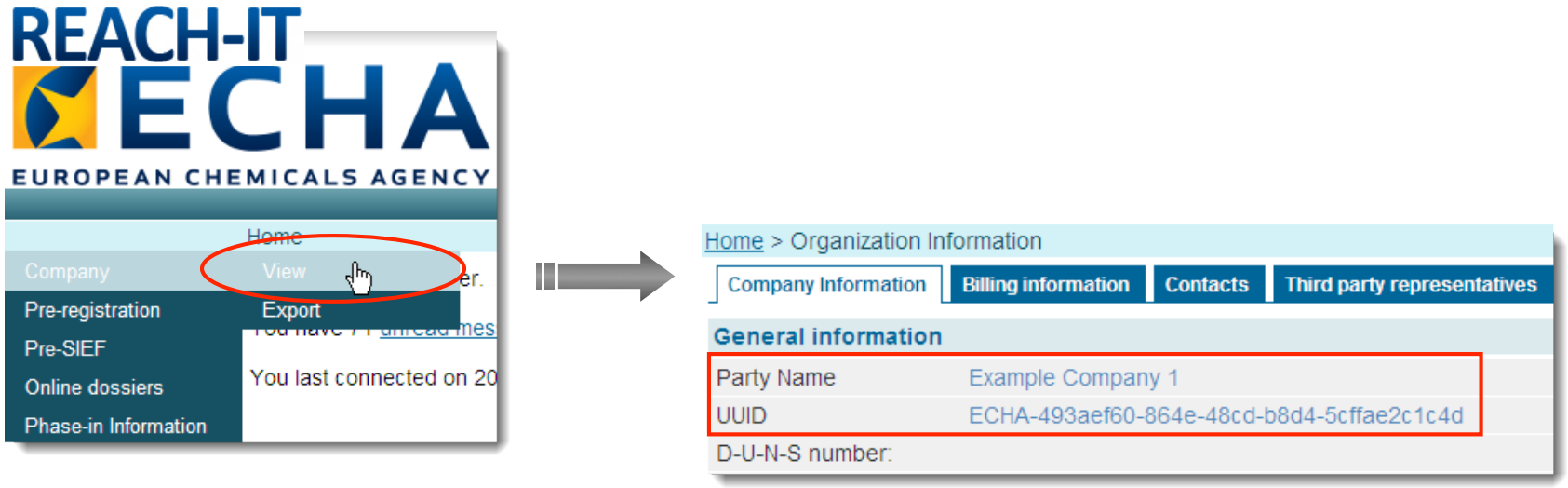
- Dossier is created from the Substance dataset:
  - includes substance information
  - administrative information needed in submission
  - READ-ONLY, cannot be modified!

- The **dossier** is the document submitted to ECHA.



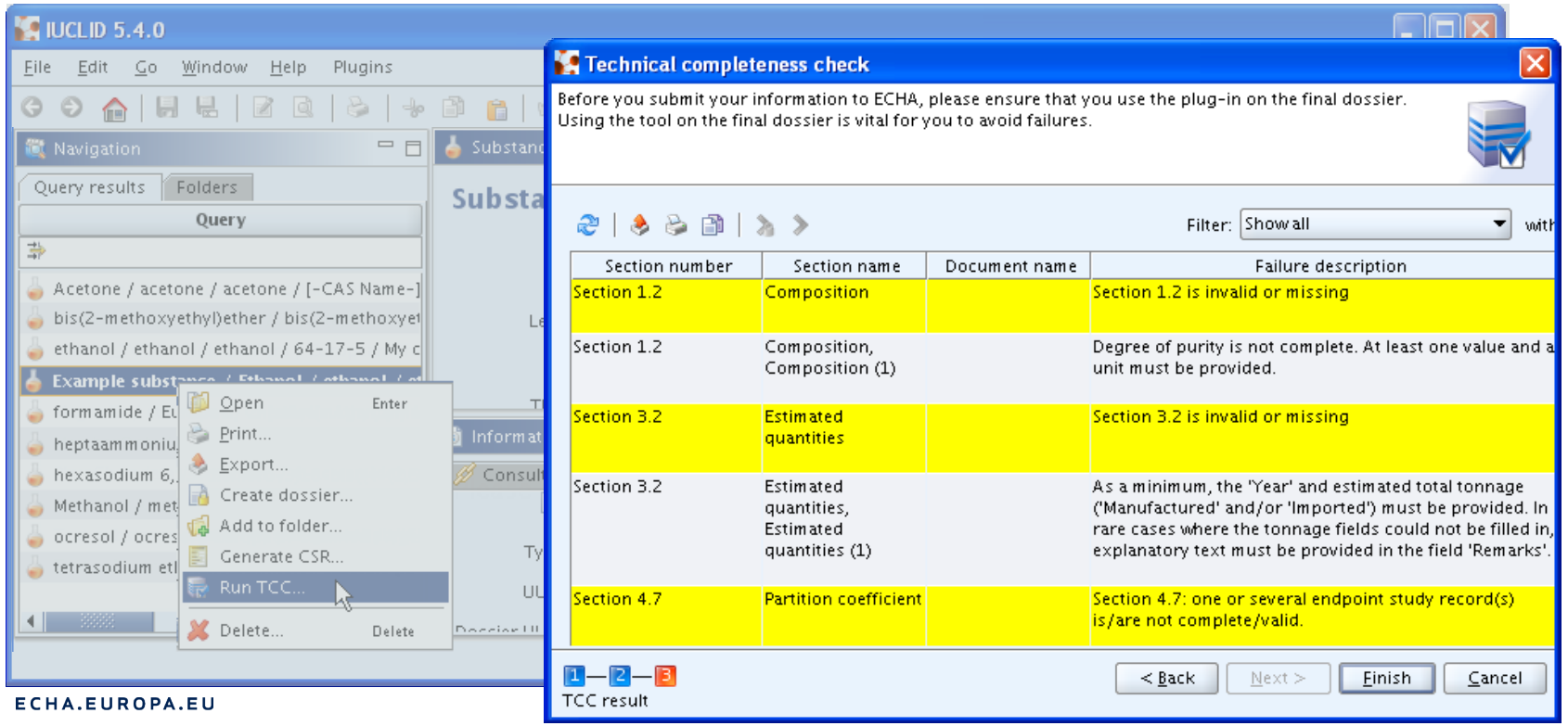
Before creating the dossier…

- Verify correct Legal entity in IUCLID:
  1. Dossier creation legal entity in IUCLID
  2. Legal entity in section 1.1 of Substance dataset
  3. Submitting company Legal entity in REACH-IT



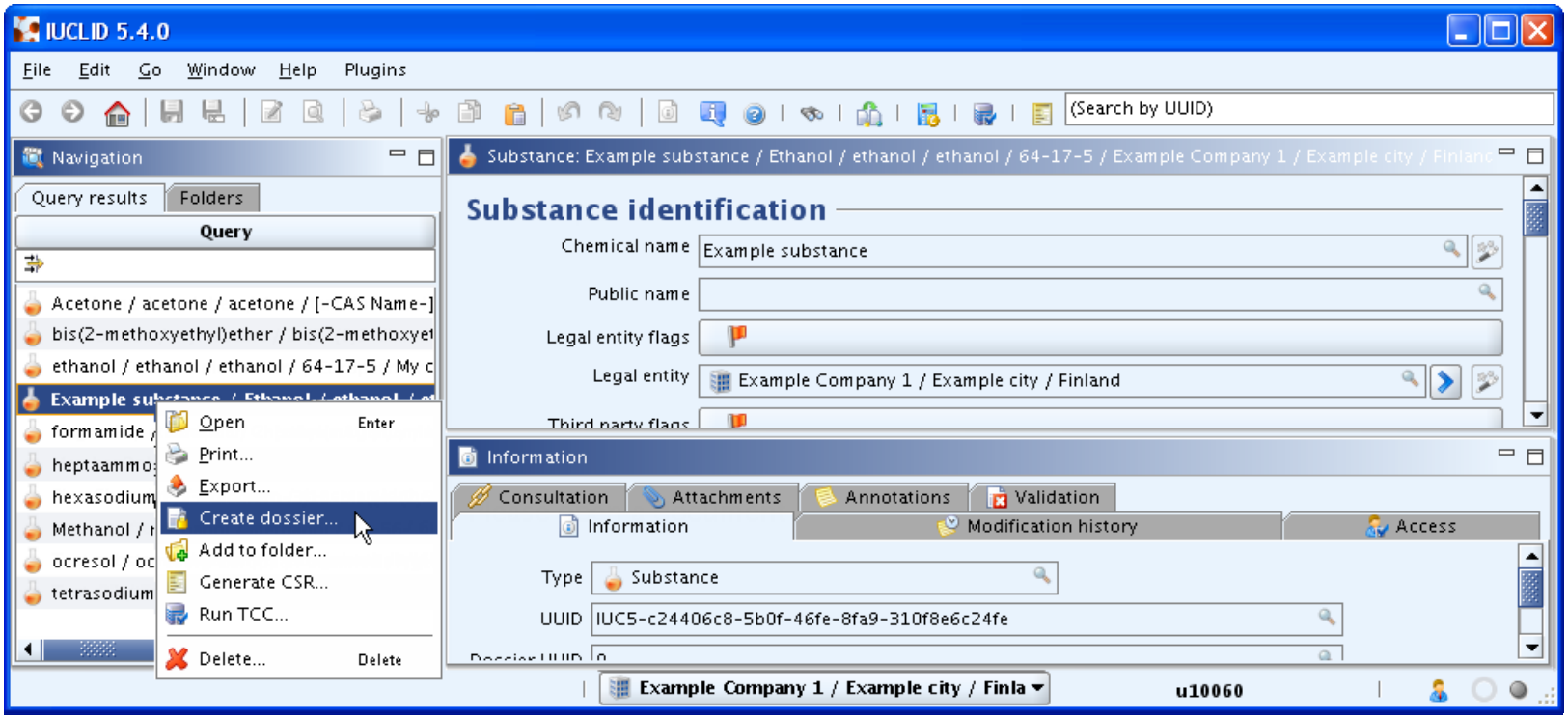
Before creating the dossier…

- Check the Technical Completeness of the Substance:
  1. Locate your Substance dataset
  2. Right-click the Substance and select ‘Run TCC’
  3. Select the appropriate dossier type in the wizard



How to create a dossier

- Locate your Substance dataset
- Right-click the Substance and select ‘Create dossier’



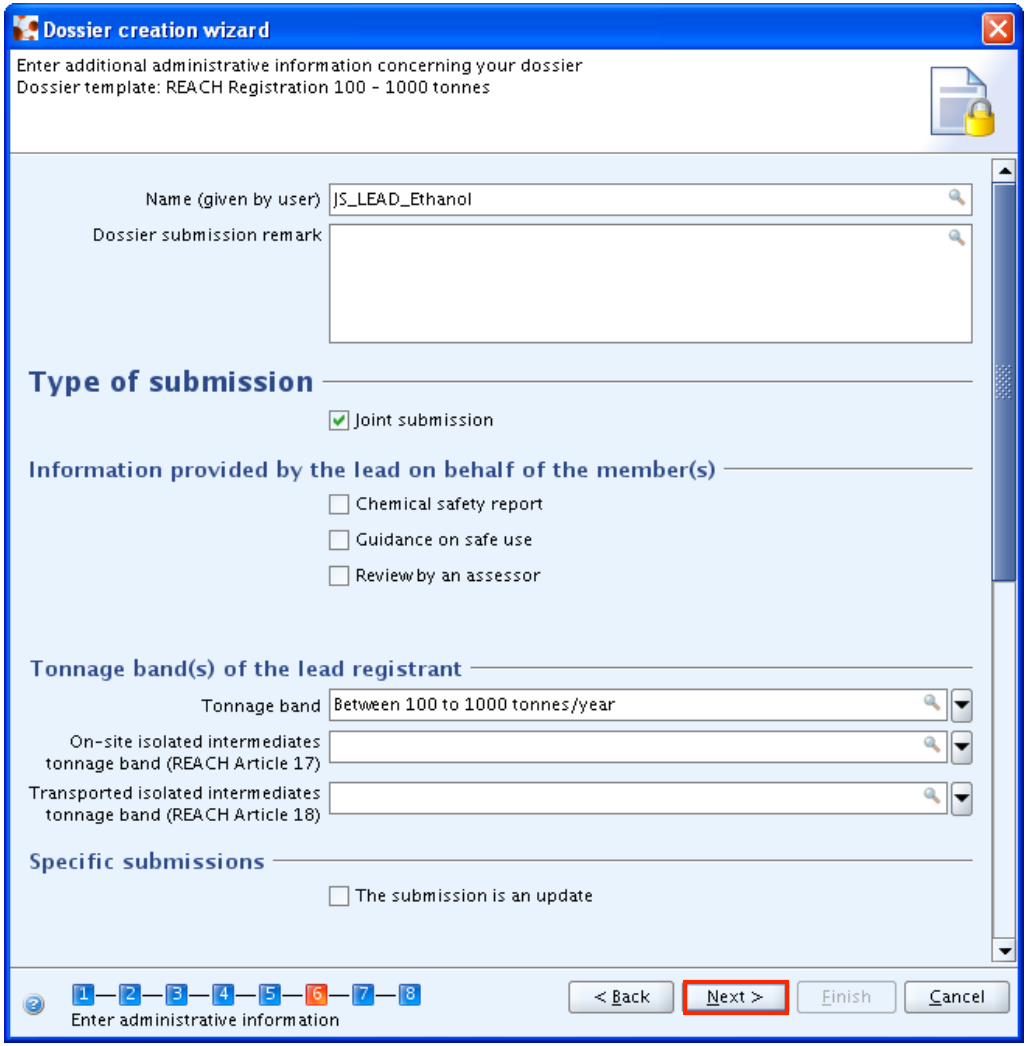
How to create a dossier

- Select the correct template
  - ➢ Template of JS tonnage band!
- Include all information

Data Submission Manual Part 4 - How to Pass Business Rule Verification ("Enforce Rules")

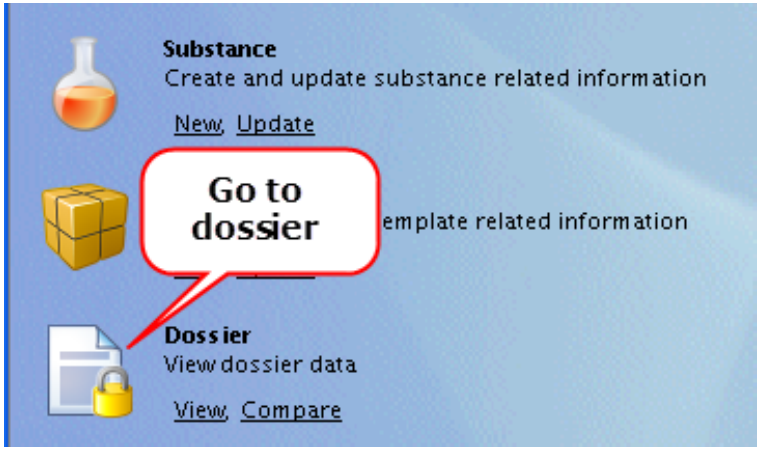
How to create a dossier

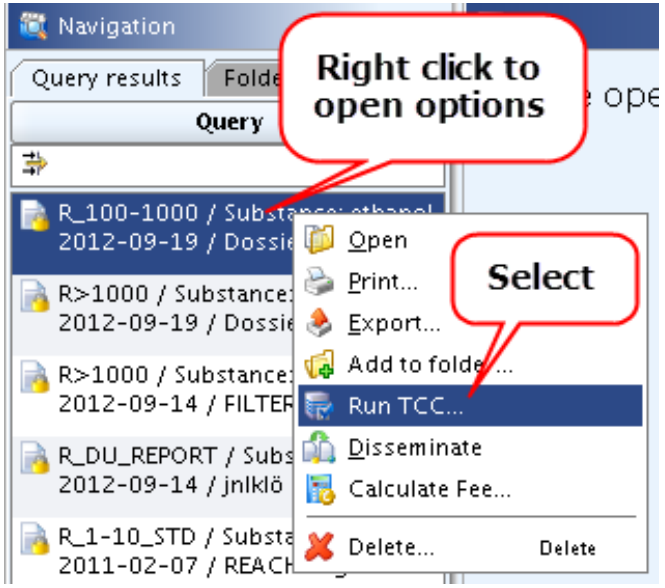
- Fill in dossier header information
- Joint submission
- Indicate here your own tonnage band
- Indicate which information you provide on behalf of the members of the JS
- Complete dossier creation wizard



Data Submission Manual Part 5 - How to Complete a Technical Dossier for Registrations and PPORD Notifications

Run the TCC plug-in once more – on your dossier

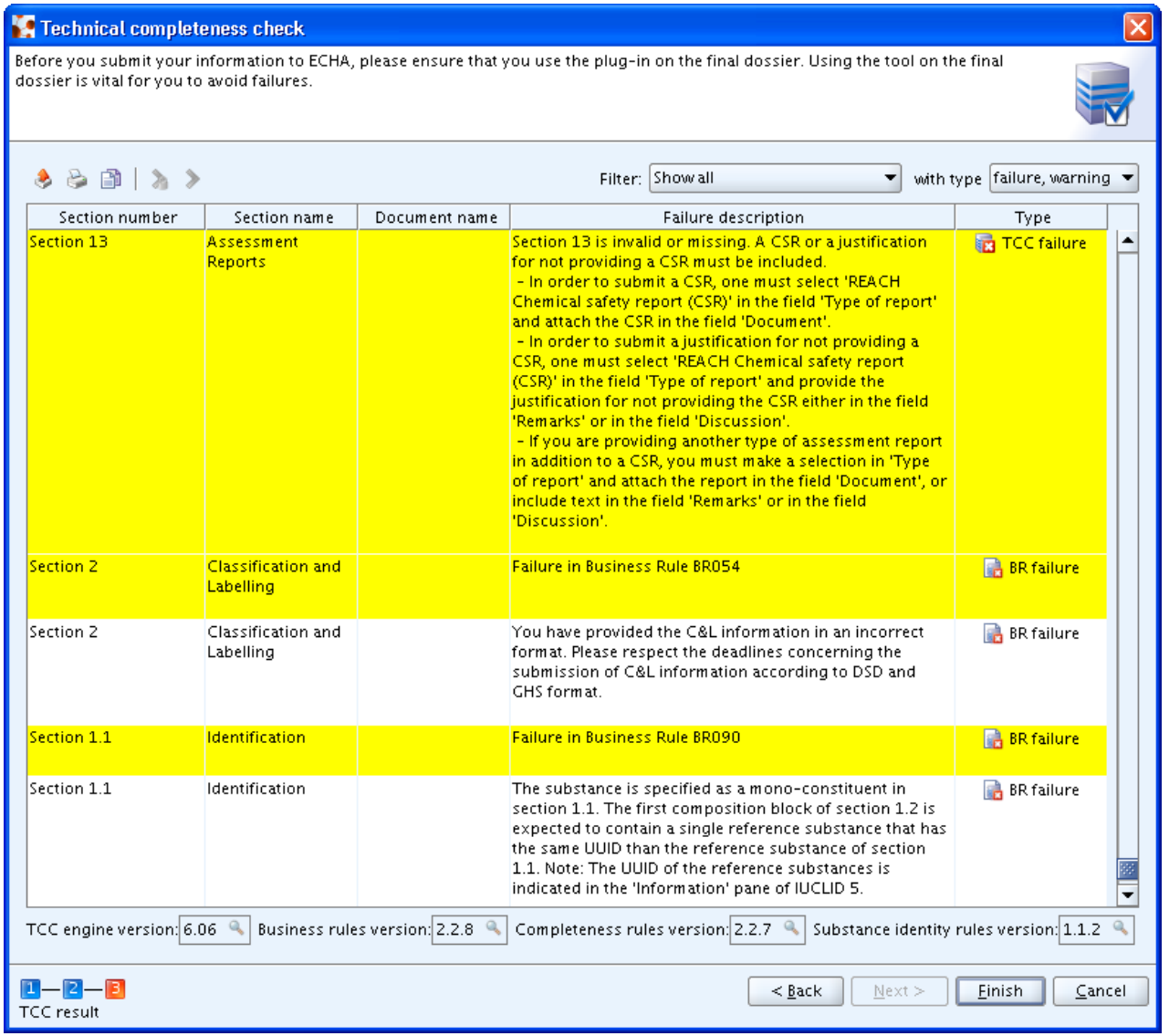




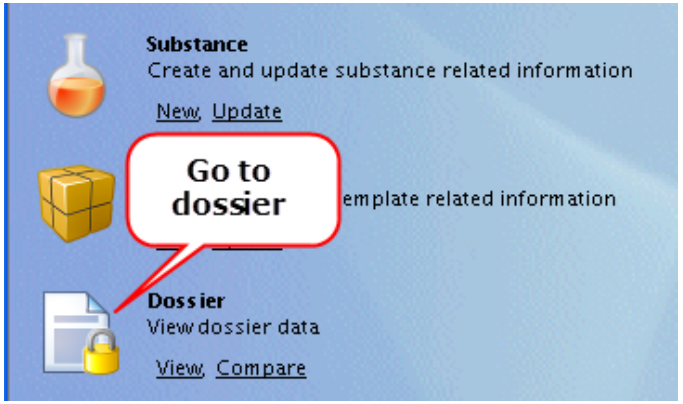
What if there are BR / TCC failures?

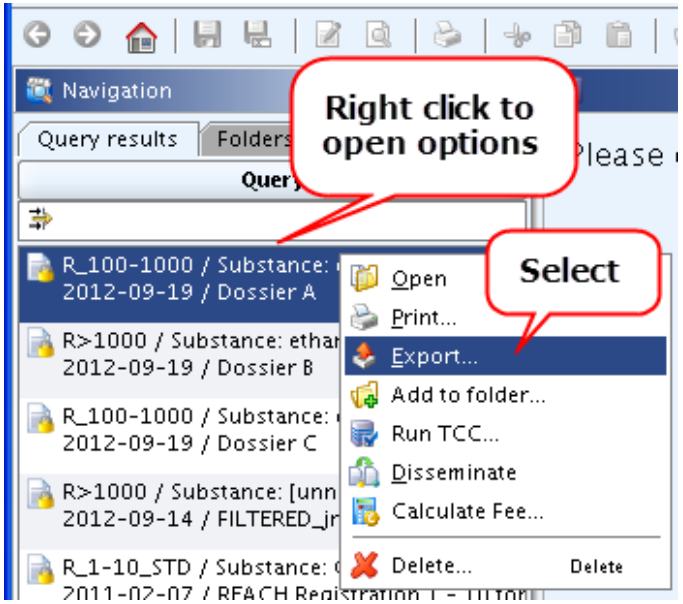
- Correct the missing / incomplete data in the substance dataset
- Create a dossier again

➢ Dossier can NOT be modified

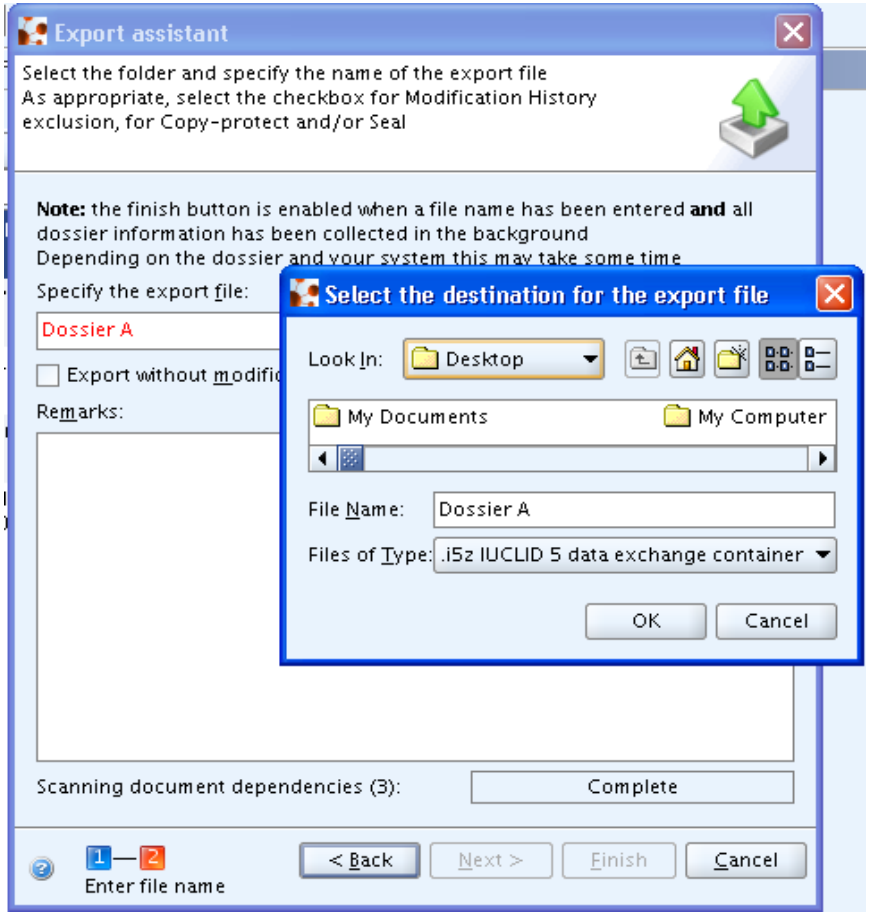


Export the dossier





- Give a name to the export file
- Export the file e.g on your desktop



Thank you

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