Basic elements of IUCLID 5

IUCLID 5.5 BASICS

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ECHA Helpdesk

14 June 2013
15:00 - 16:30 (EEST GMT +3)

Outline

- **What is the Substance dataset**
  - Main IUCLID 5 sections

- **How to fill in the Substance dataset**

  - Sections 1.1 and 1.2
    - Linking of a reference substance
  - Sections 4 – 7
    - How to create an endpoint study record
  - Section 13
    - How to attach a Report

- **Creating and exporting a dossier**

What is the substance dataset

What is a substance dataset

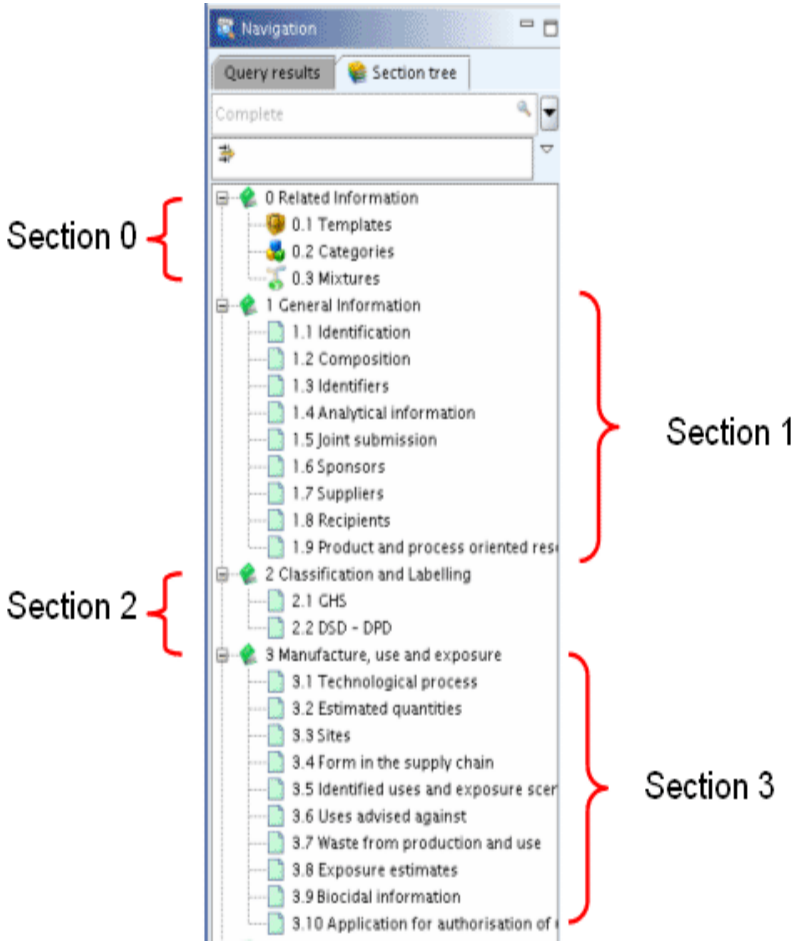
- Central core of information in IUCLID
  - It contains all data related to a chemical substance (chemical identity and all required and available endpoint study summaries)
  - Repository of data, which is used as a basis to create a registration Dossier

Substance dataset, sections 0-3

A root element – Main entity

- It carries the information on all Legal entity(-ies) and Reference substance(s) related to the Substance.

When a Substance dataset is exported or a Dossier is created out of it, everything connected to the root element is always included.



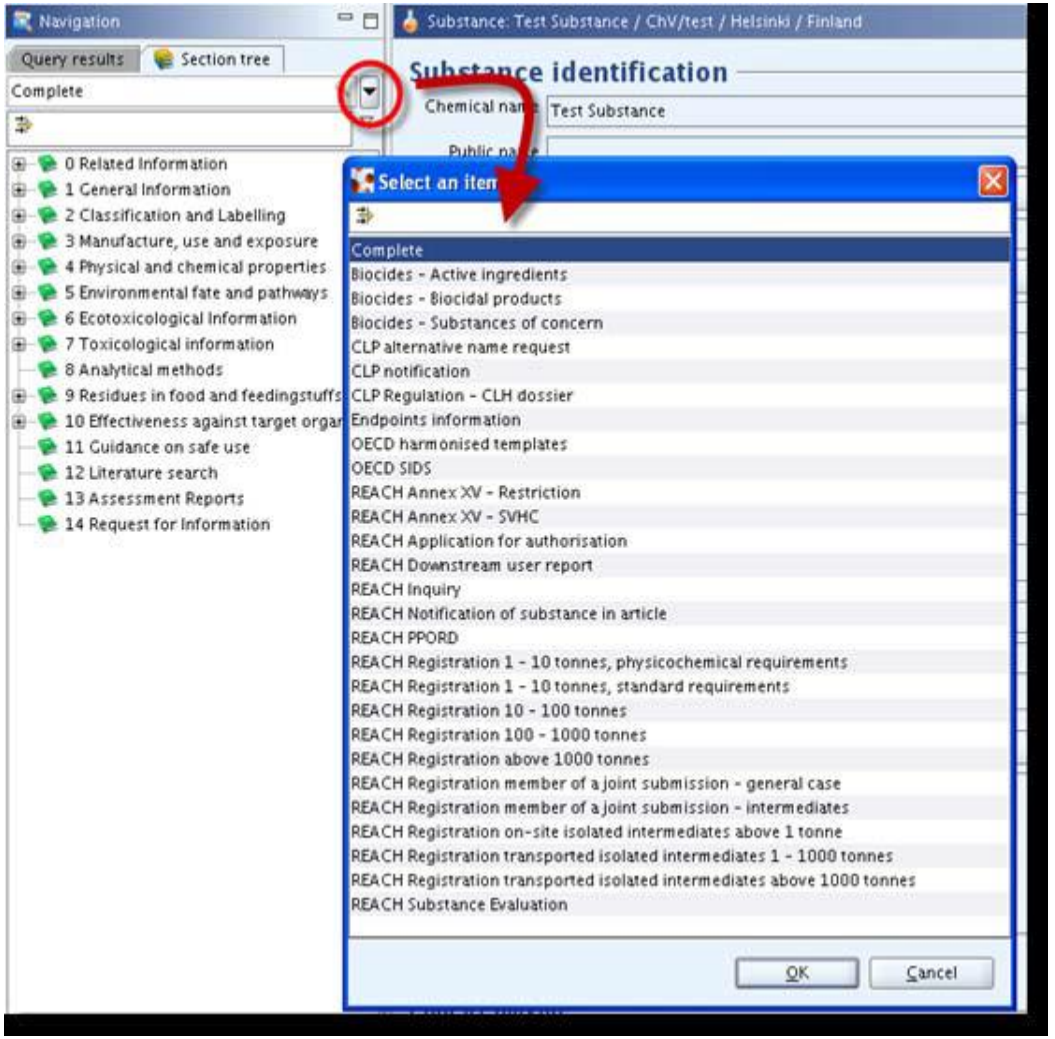
Substance dataset, sections 4-14

Multiple endpoint elements

- Endpoint Sections 4 - 14 are the containers for Endpoint study records and Endpoint summary records.
Every Endpoint record always belongs to a Substance dataset.
- Every Endpoint section can have multiple Endpoint **study** records and one Endpoint **summary**

How to select a template

- Click on the black arrow
- Select the appropriate template



How to fill in the substance dataset

How to fill in a Substance dataset

- **Creation of a new Substance dataset**
- Sections 1.1 and 1.2
  - Linking of a reference substance
- Sections 4 – 7
  - How to create an endpoint study record
- Section 13
  - How to attach a Report
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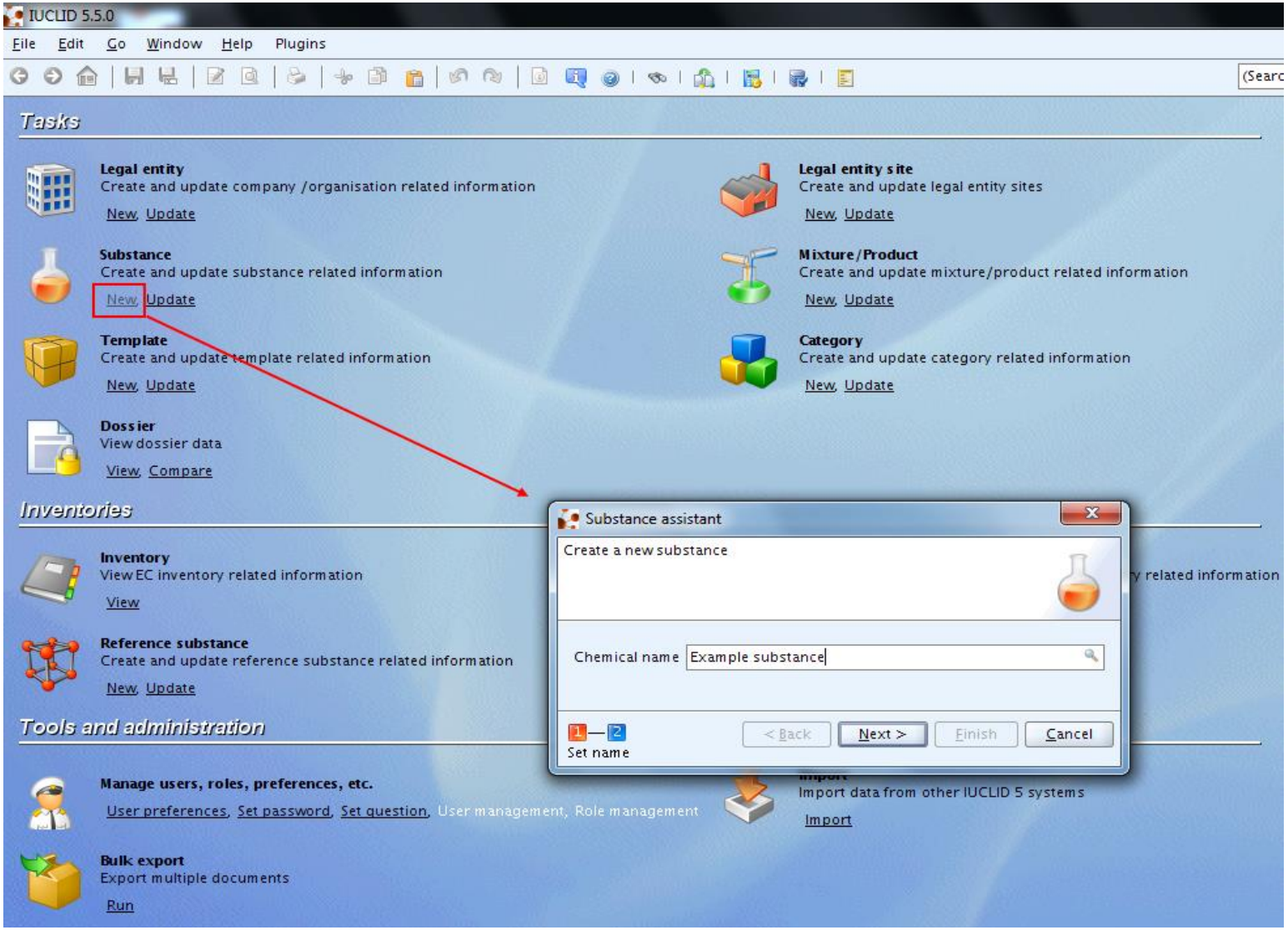
Creation of a new Substance dataset



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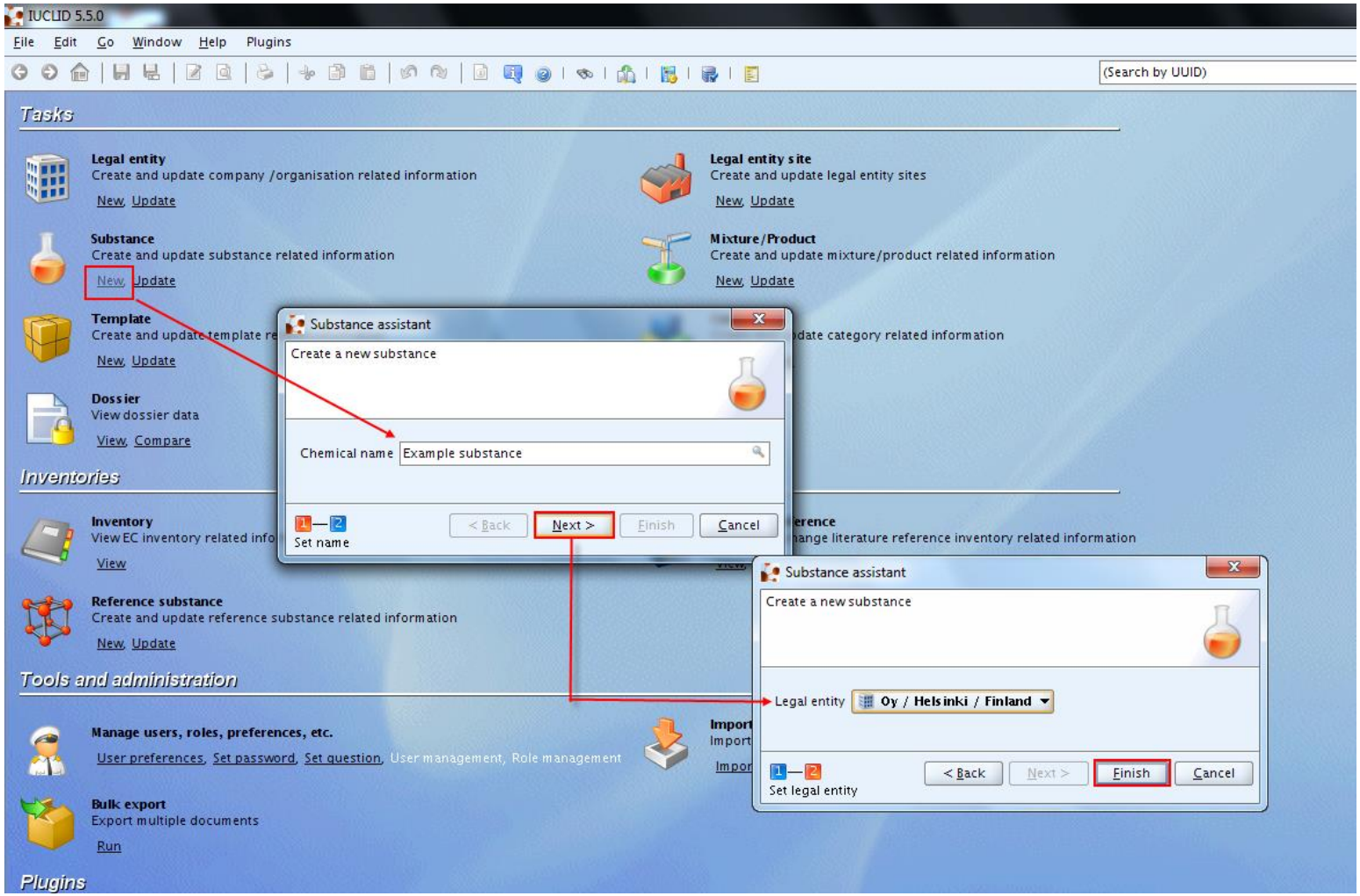

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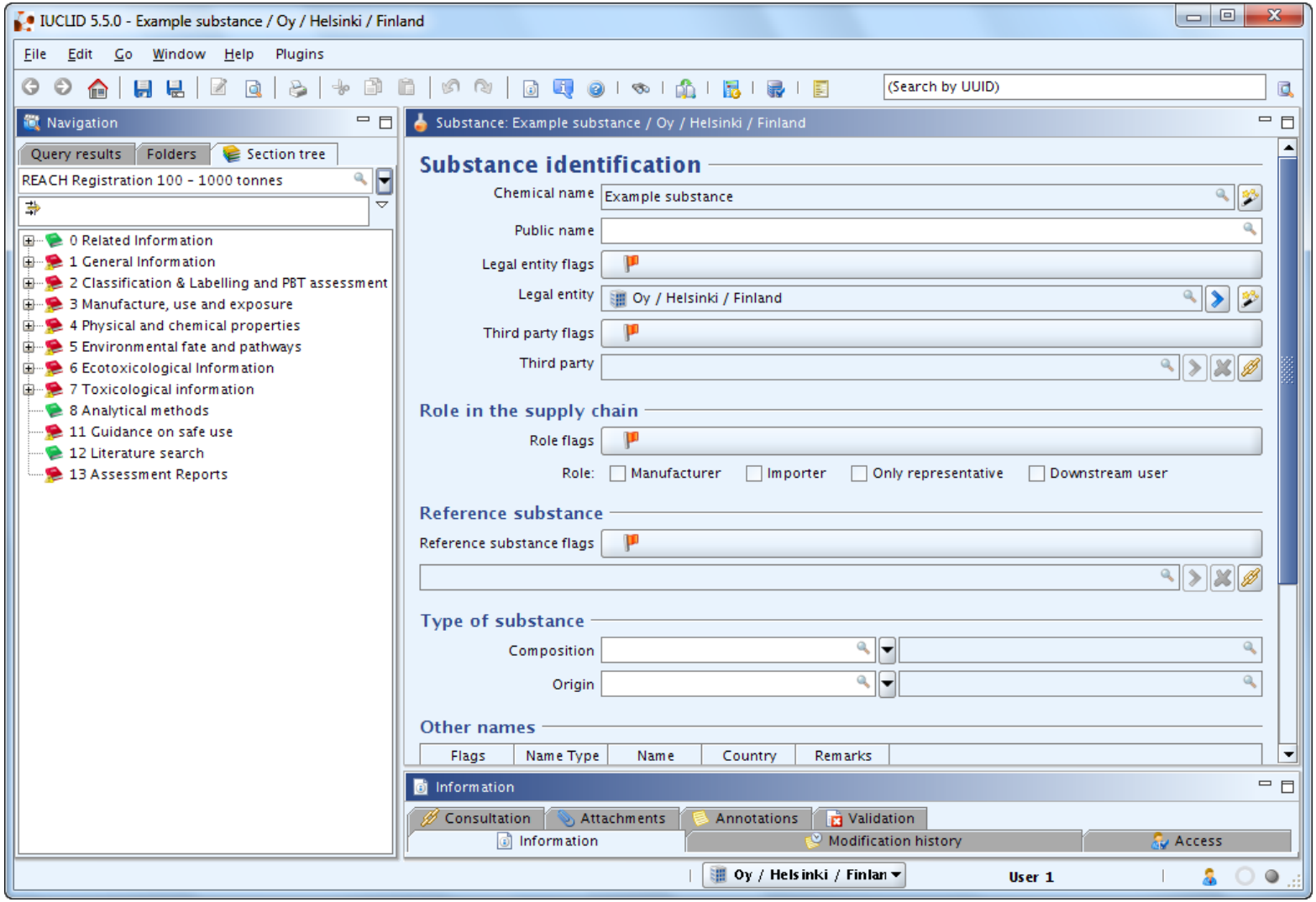

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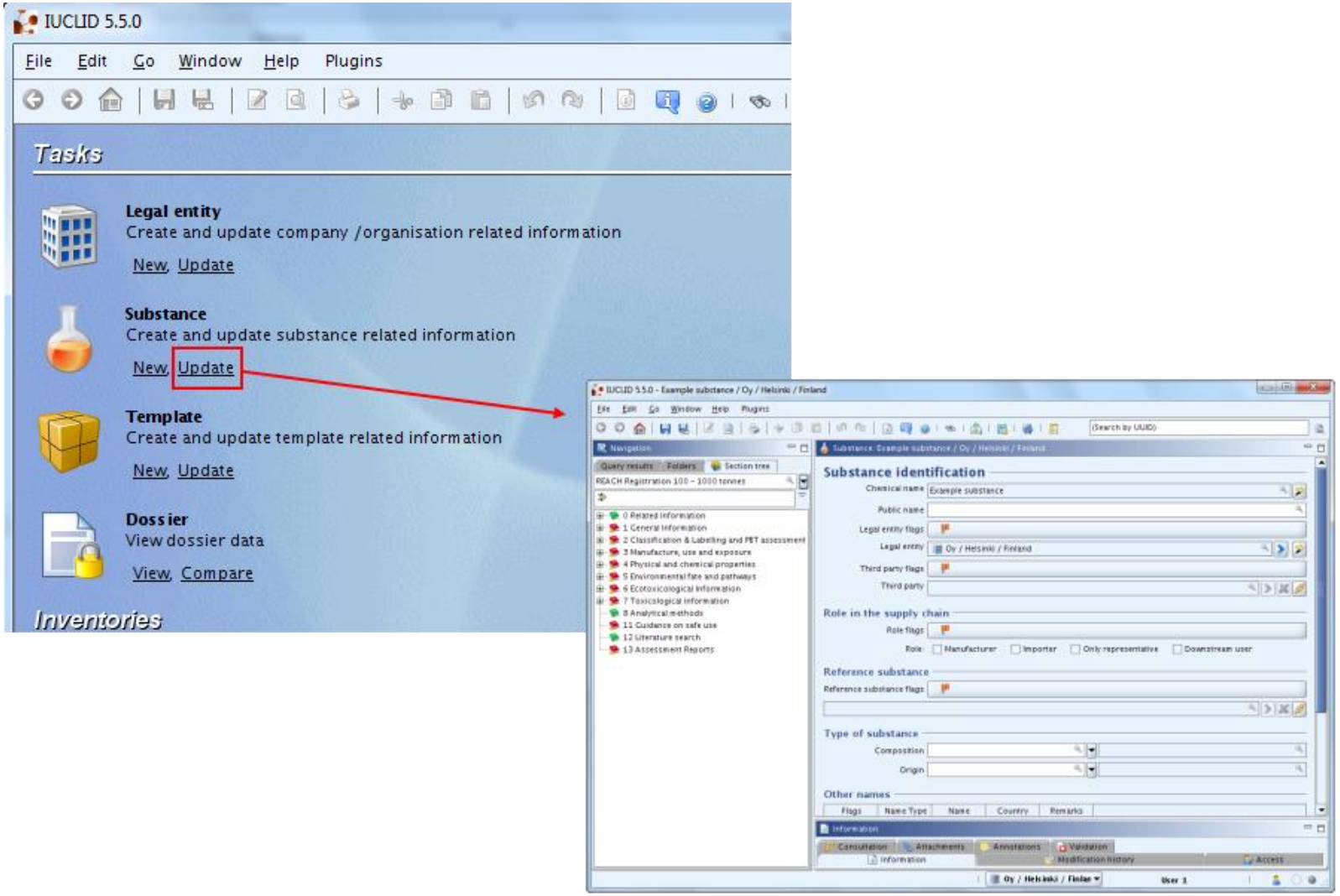

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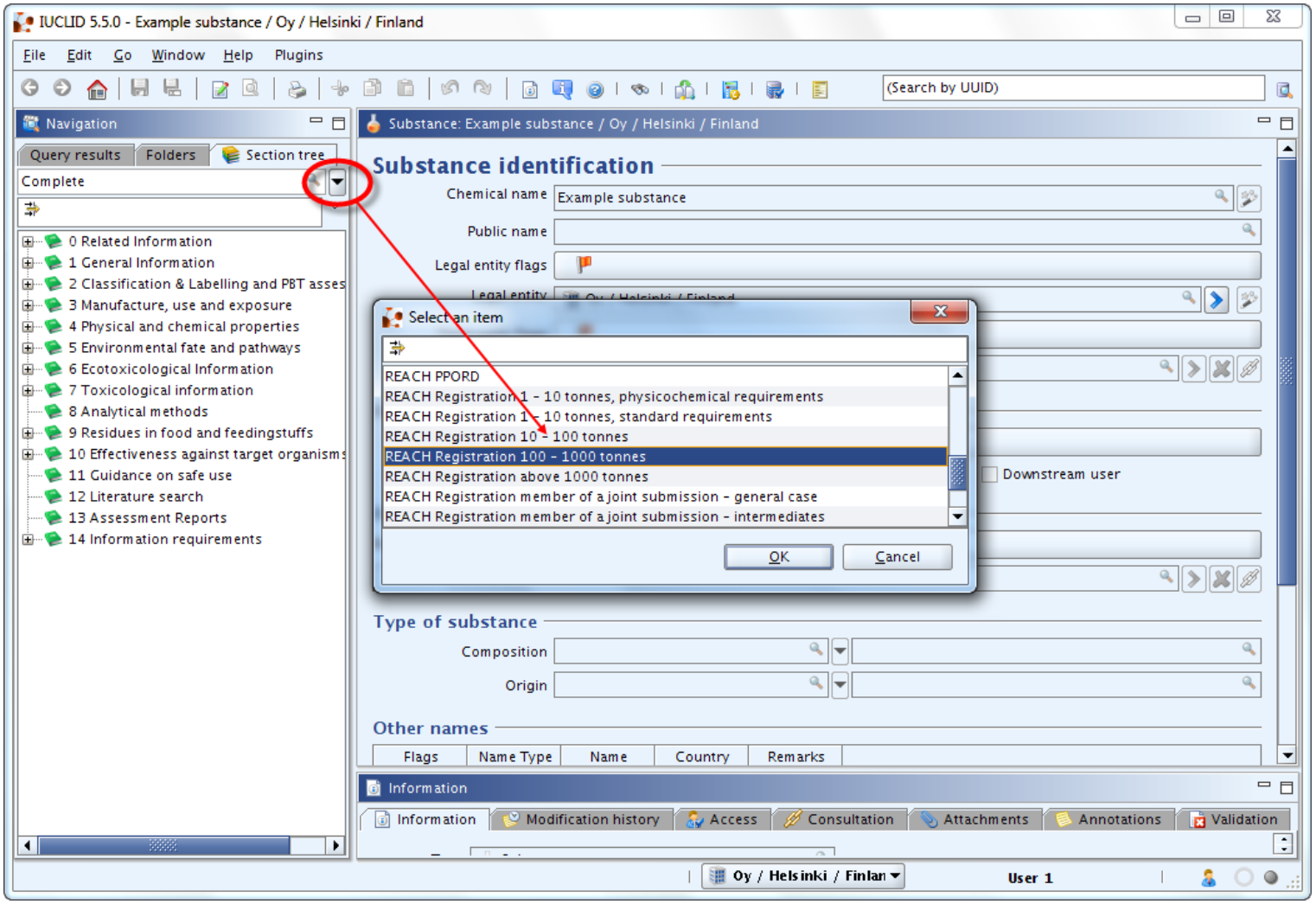

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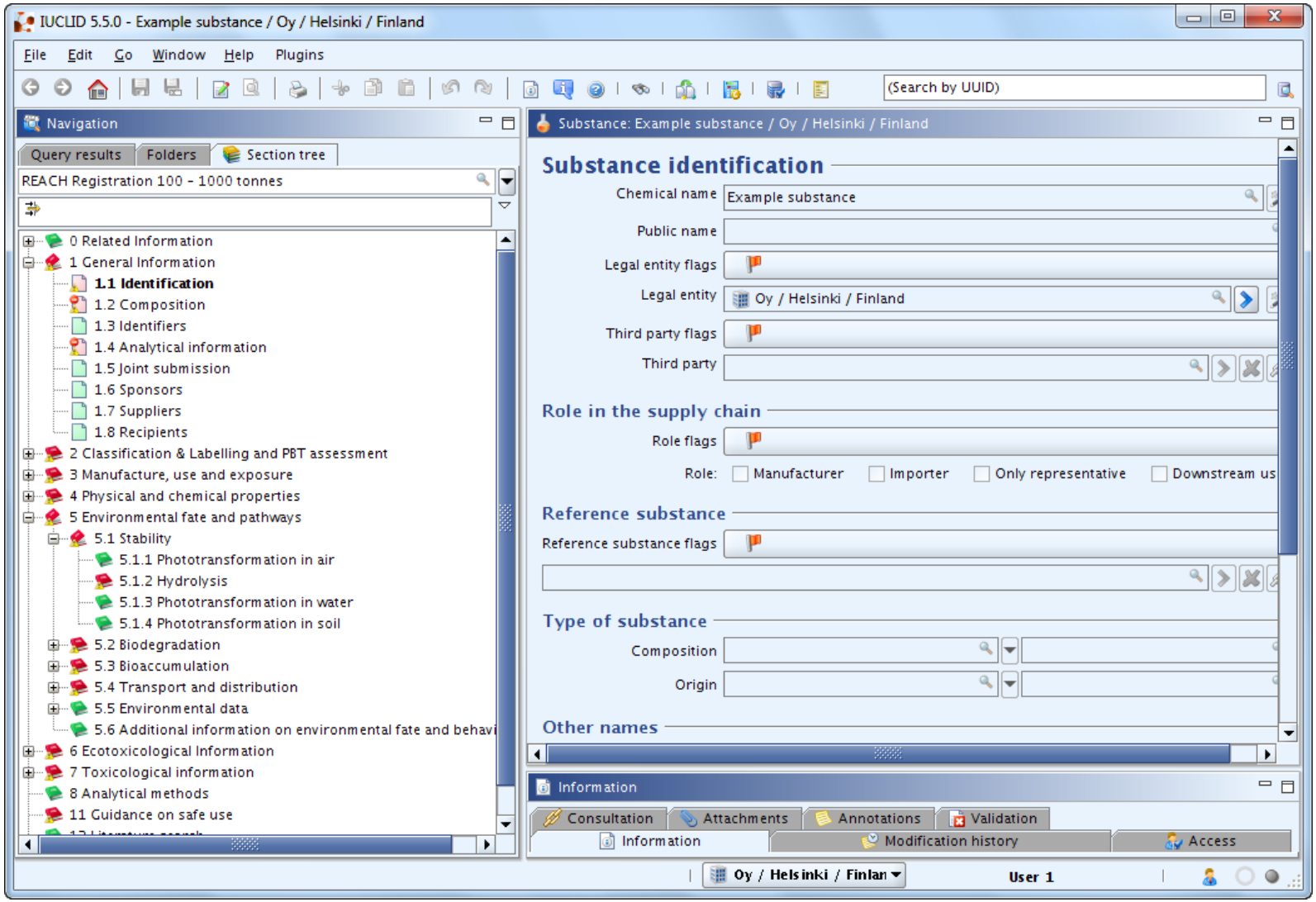

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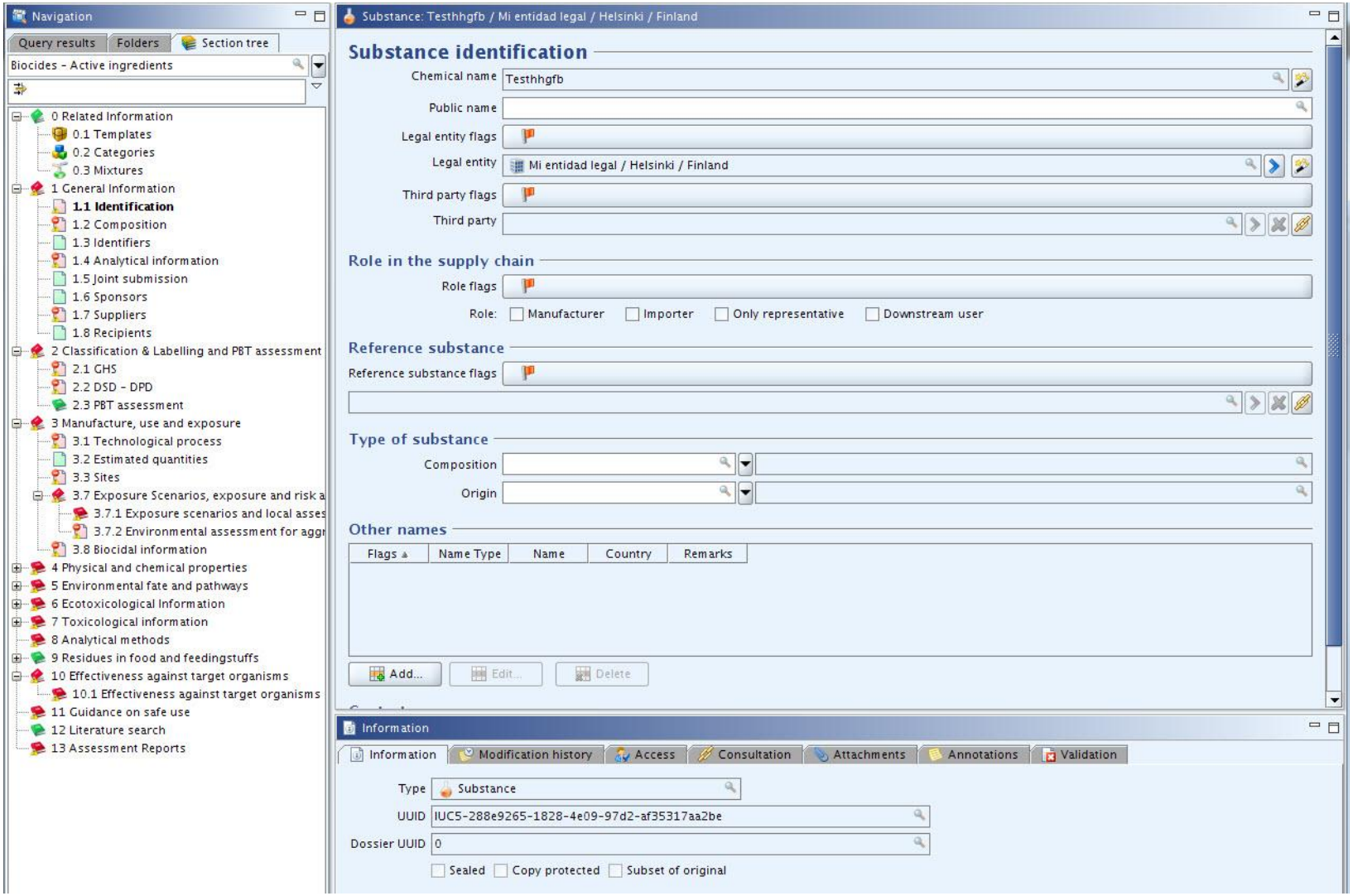
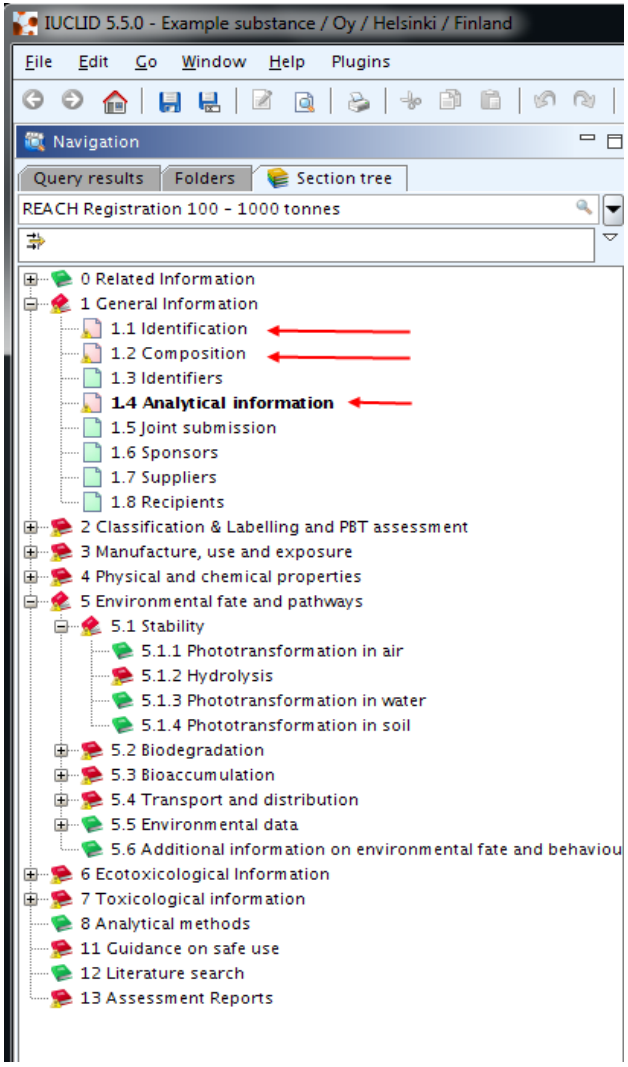


How to fill in a Substance dataset

- Creation of a new Substance dataset
- **Sections 1.1 and 1.2**
  - **Linking of a reference substance**
- Sections 4 – 7
  - How to create an endpoint study record
- Section 13
  - How to attach a Report
- Creating and exporting a dossier

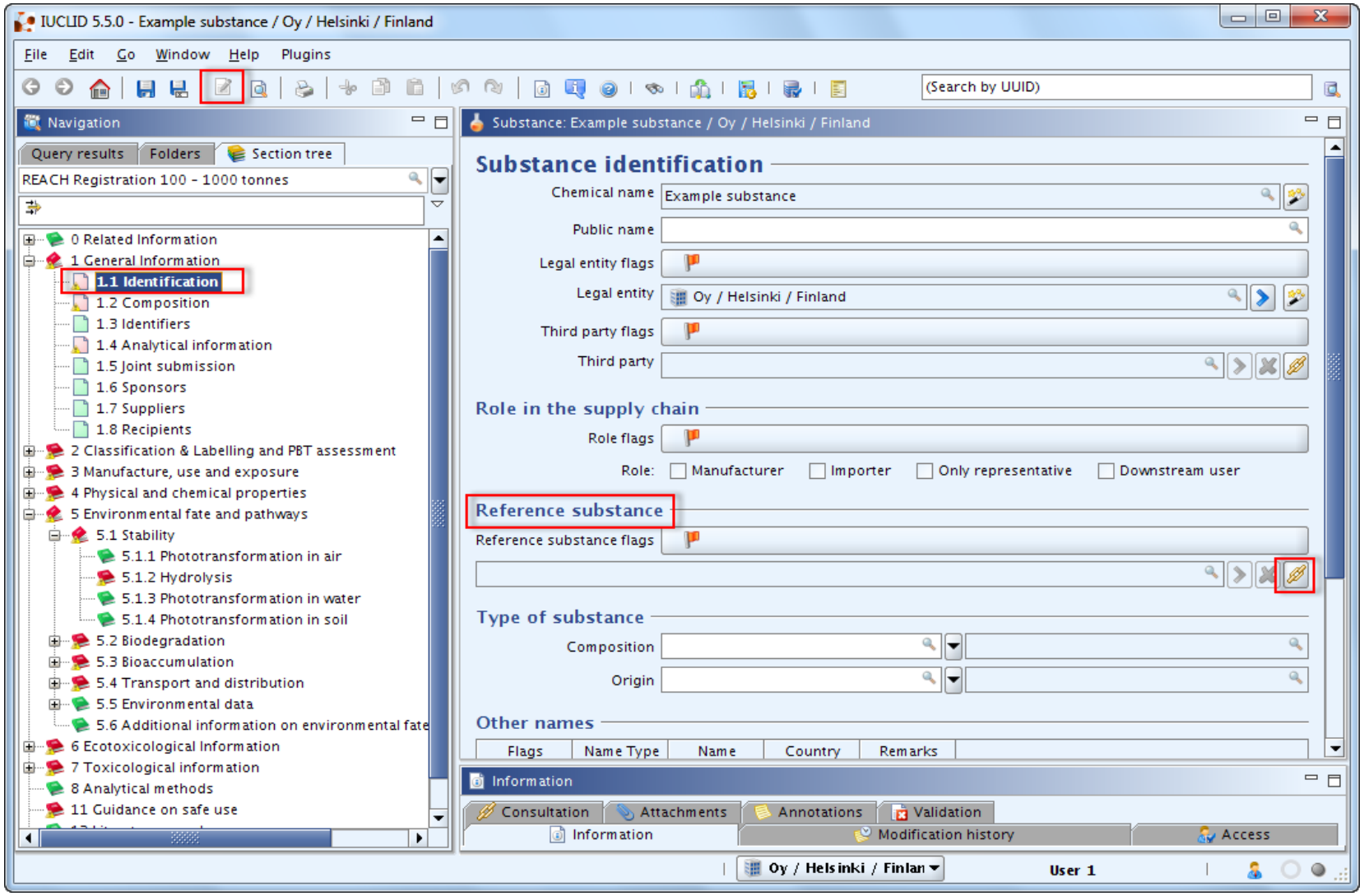
Sections 1.1 and 1.2 – Reference substance



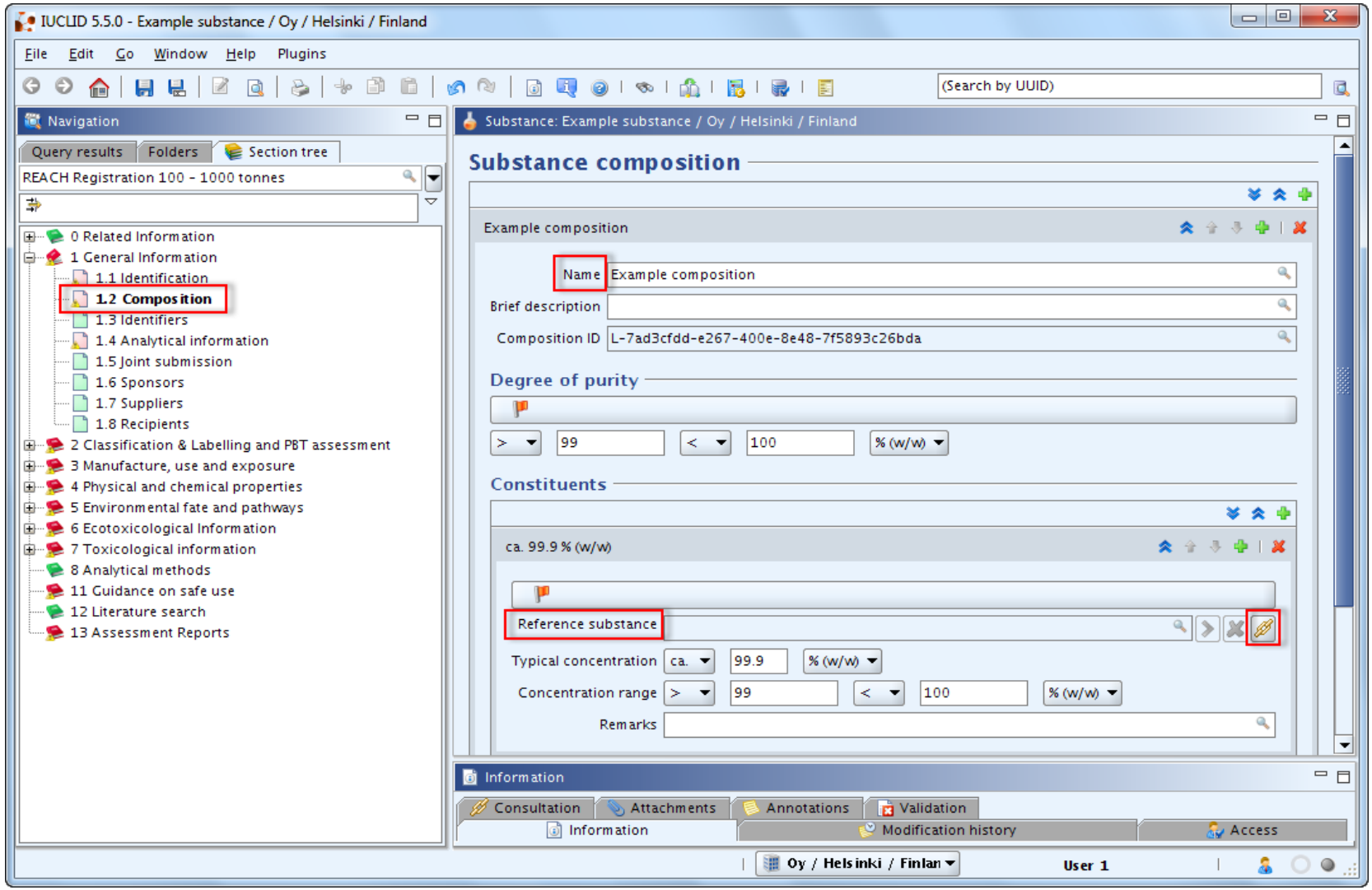
Data Submission Manual Part 18 - How to report the substance identity in IUCLID 5 for registration under REACH

Guidance for identification and naming of substances under REACH and CLP

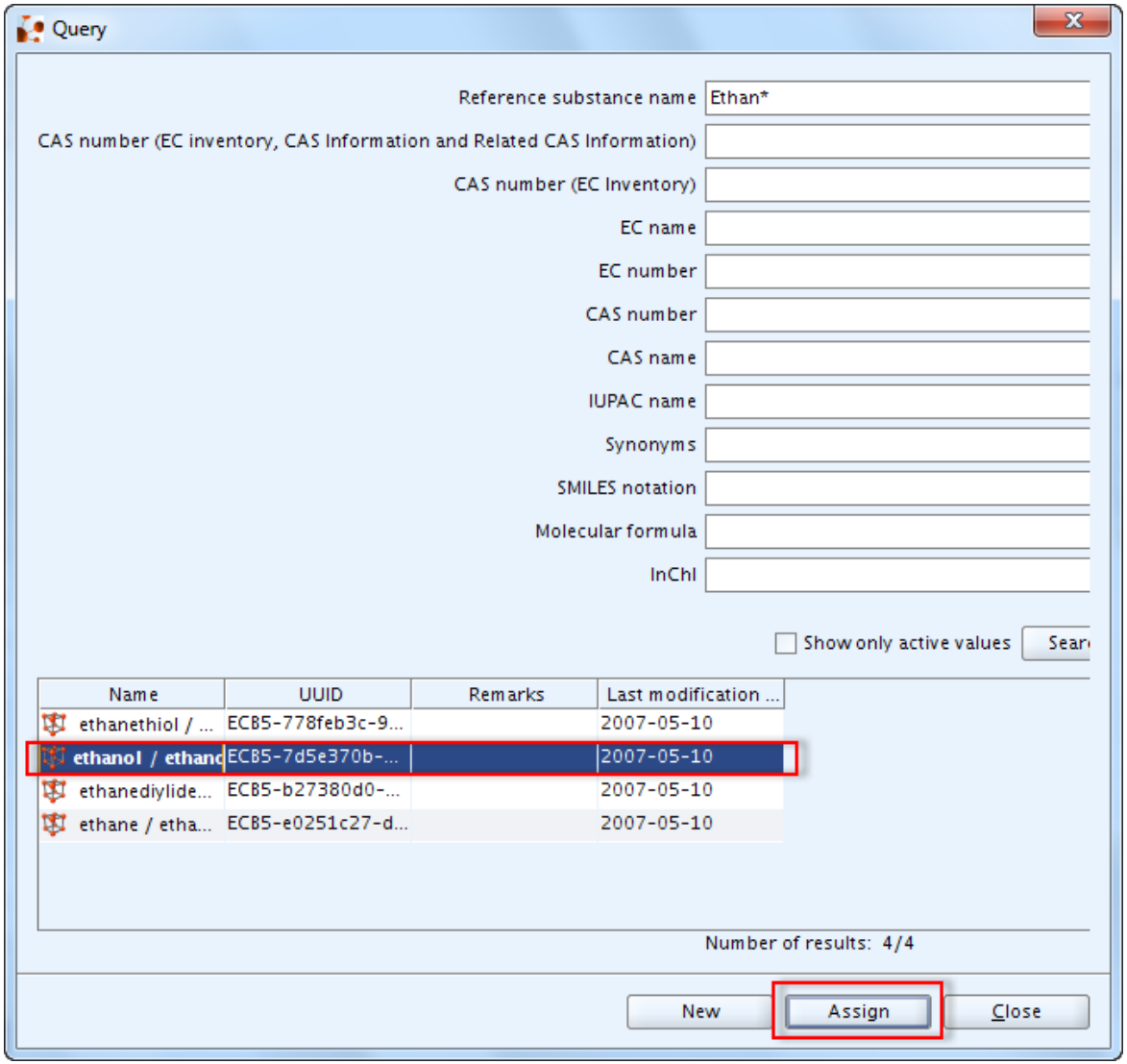
Sections 1.1 and 1.2 – Reference substance



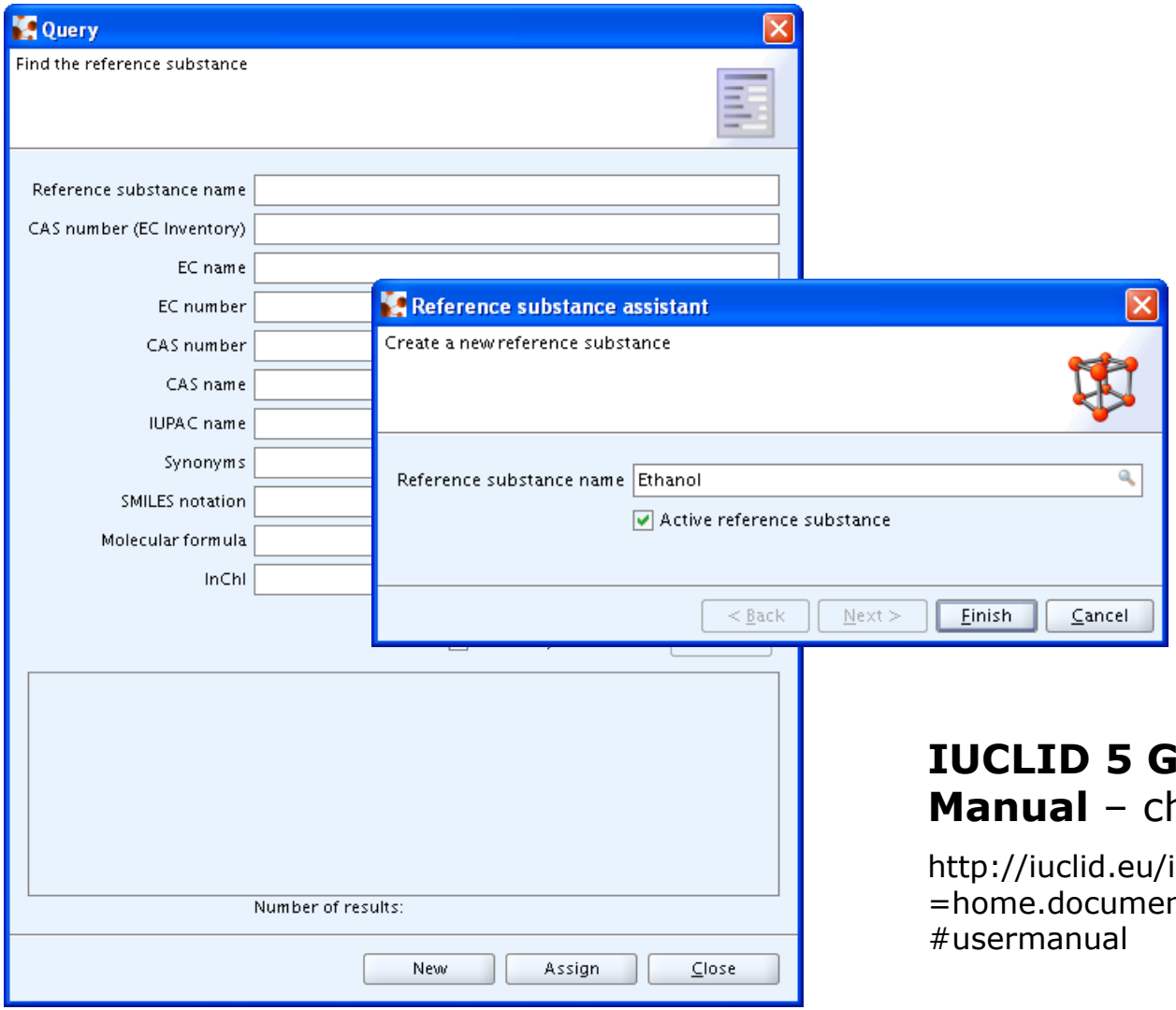
Sections 1.1 and 1.2 – Reference substance



Linking an existing Reference substance



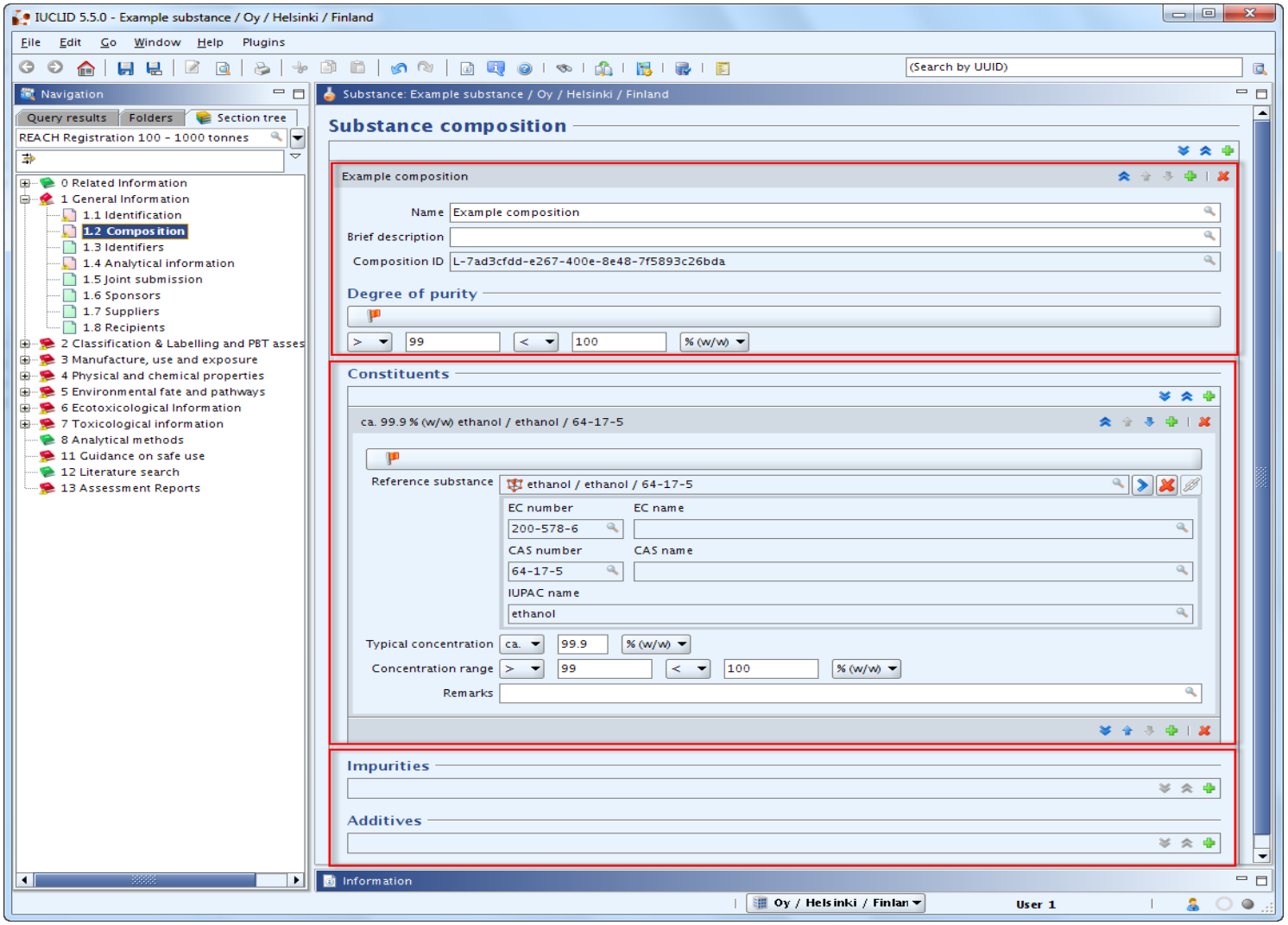
Creating a new Reference substance



IUCLID 5 Getting Started Manual – chapter 3

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

Sections 1.1 and 1.2 – Reference substance



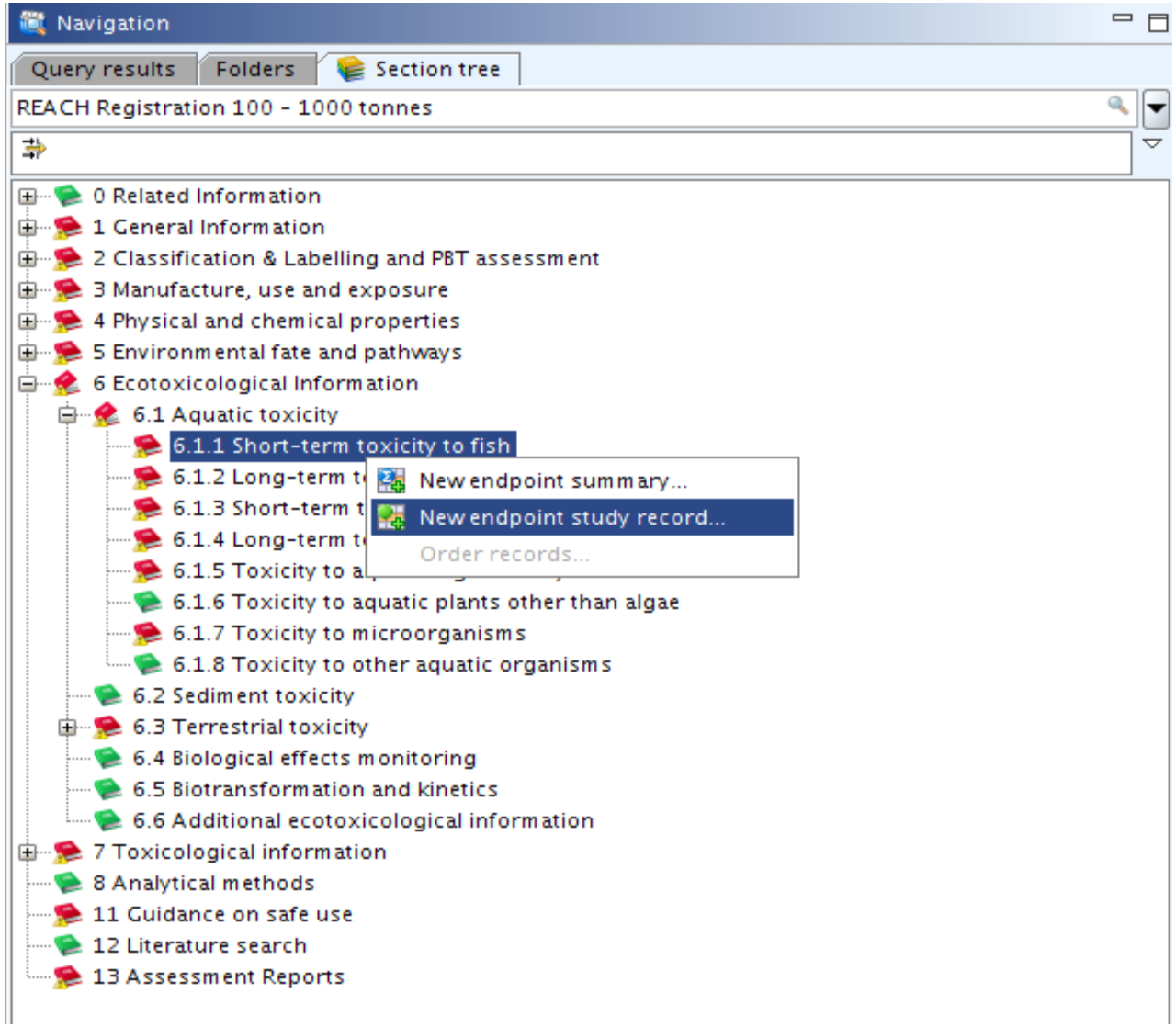
How to fill in a Substance dataset

- Creation of a new Substance dataset
- Sections 1.1 and 1.2
  - Linking of a reference substance
- **Sections 4 – 7**
  - **How to create an endpoint study record**
- Section 13
  - How to attach a Report
- Creating and exporting a dossier

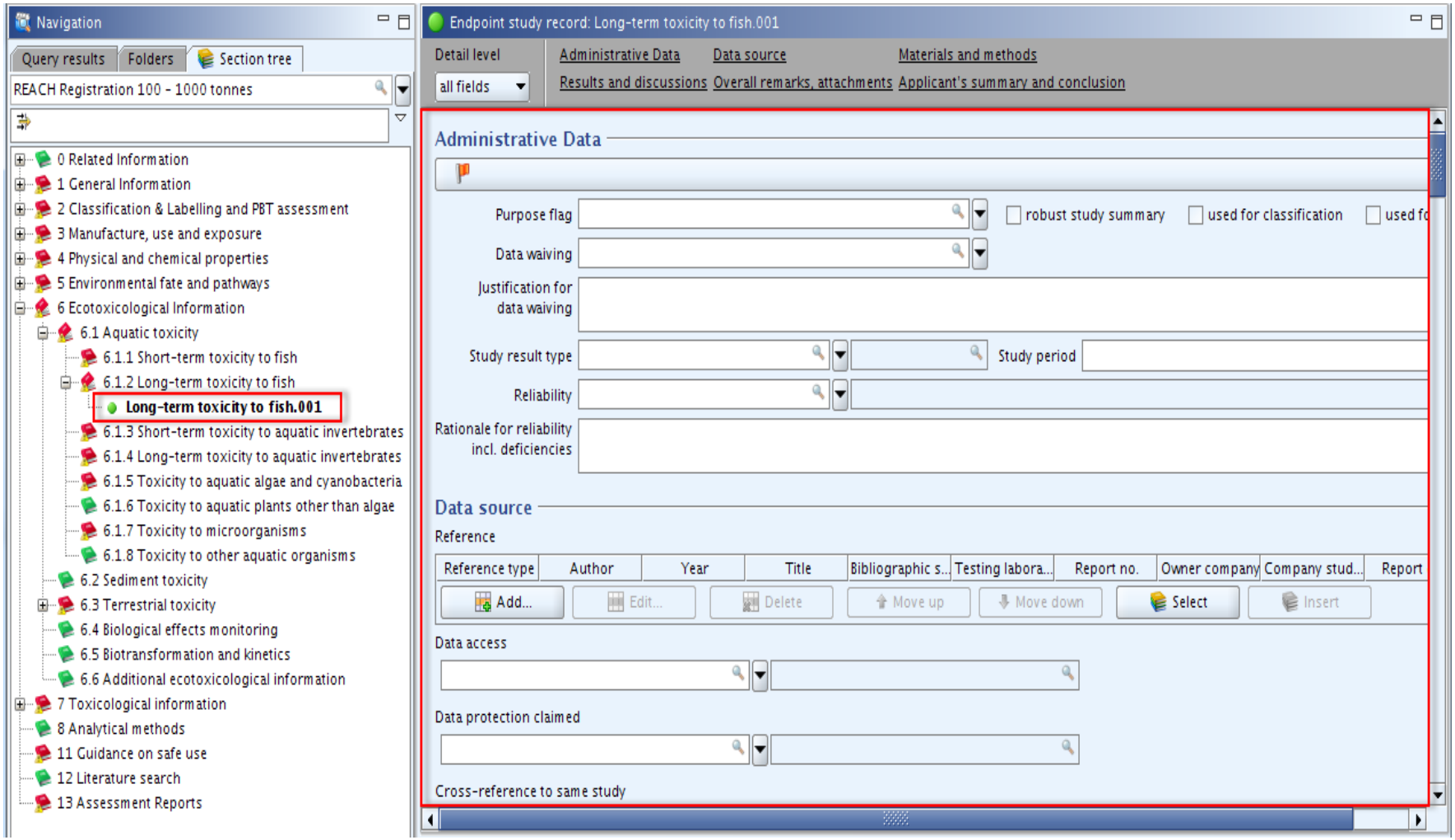
Creation of endpoint study records

- 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



Creation of endpoint study records



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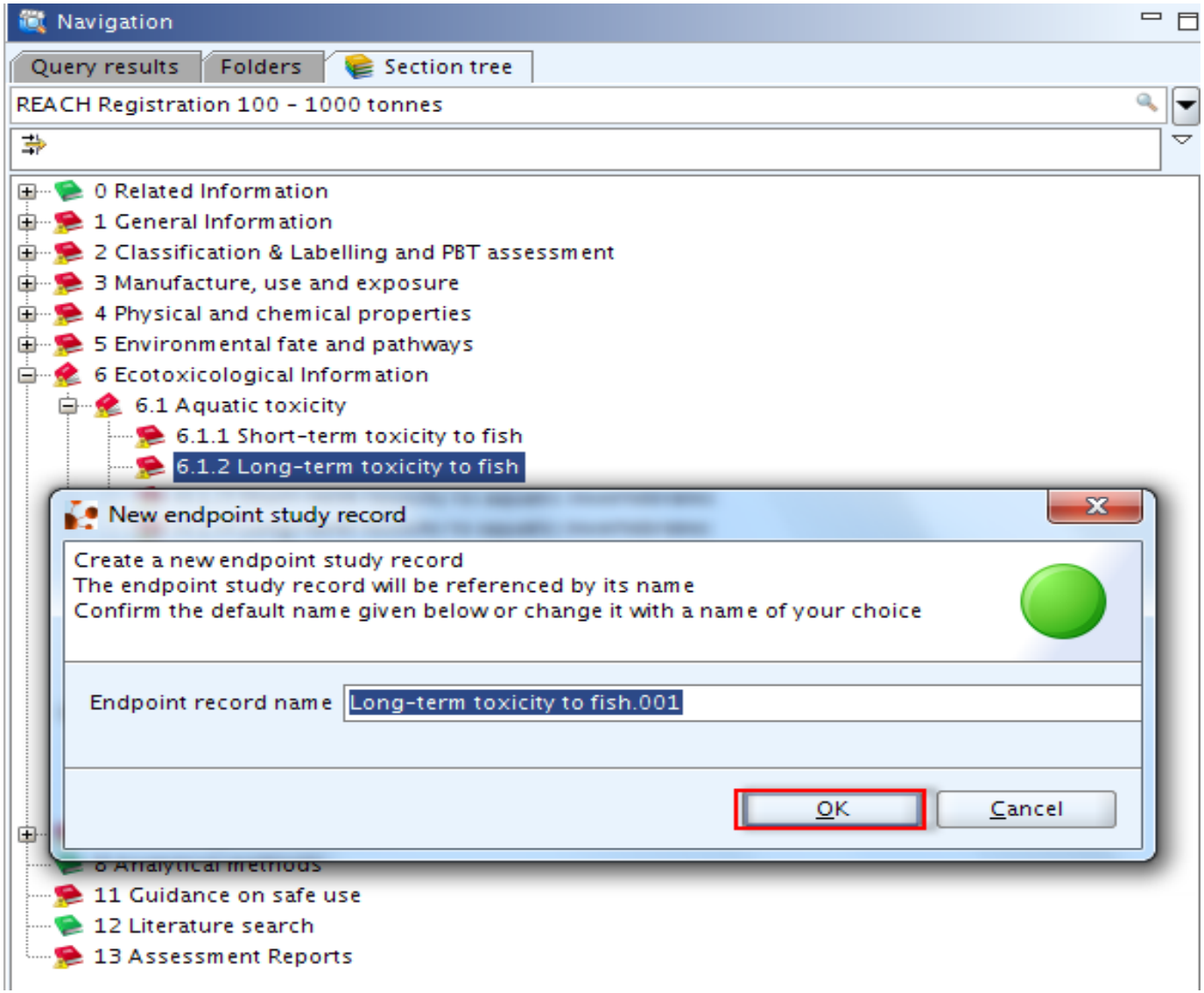

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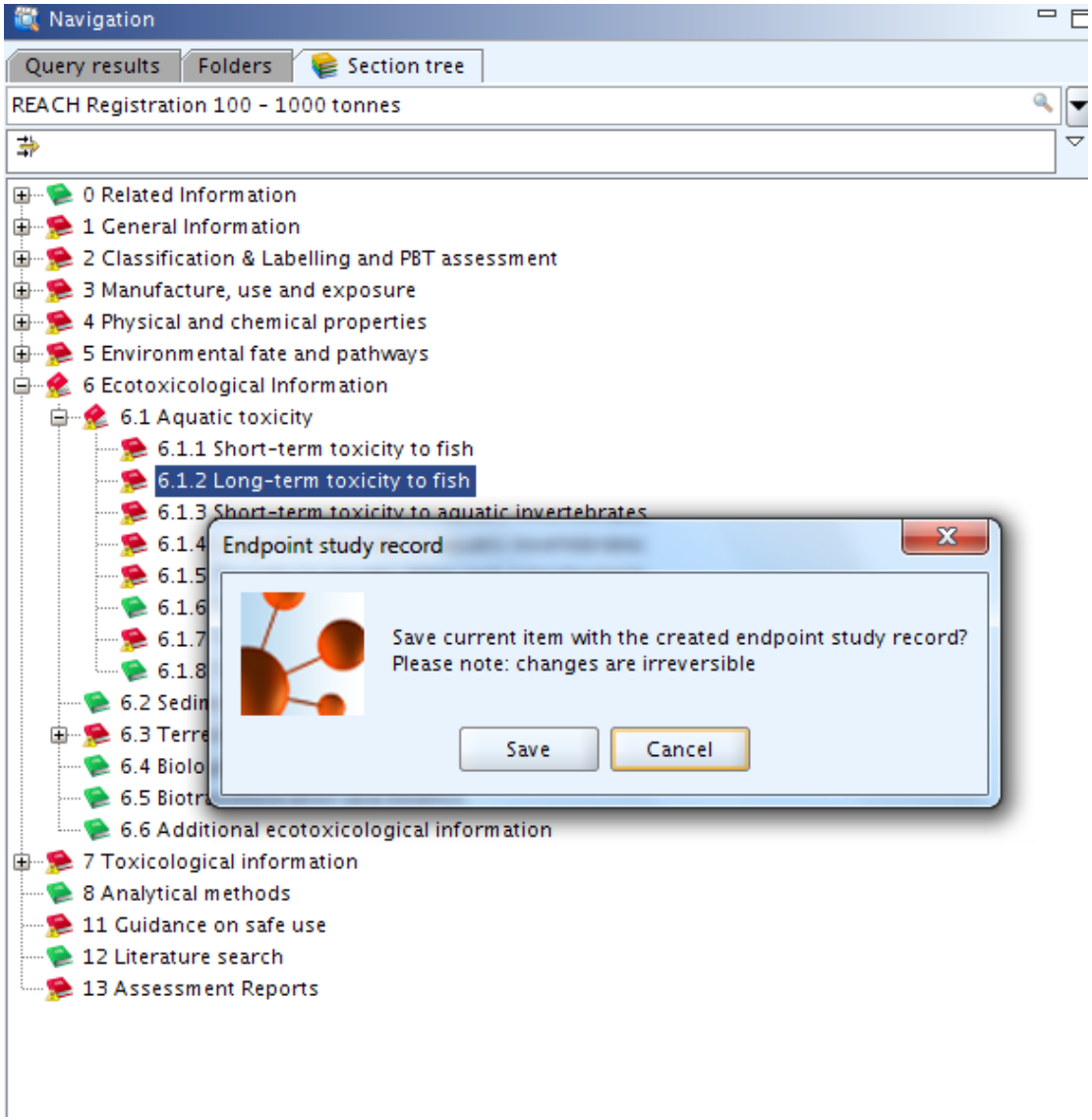

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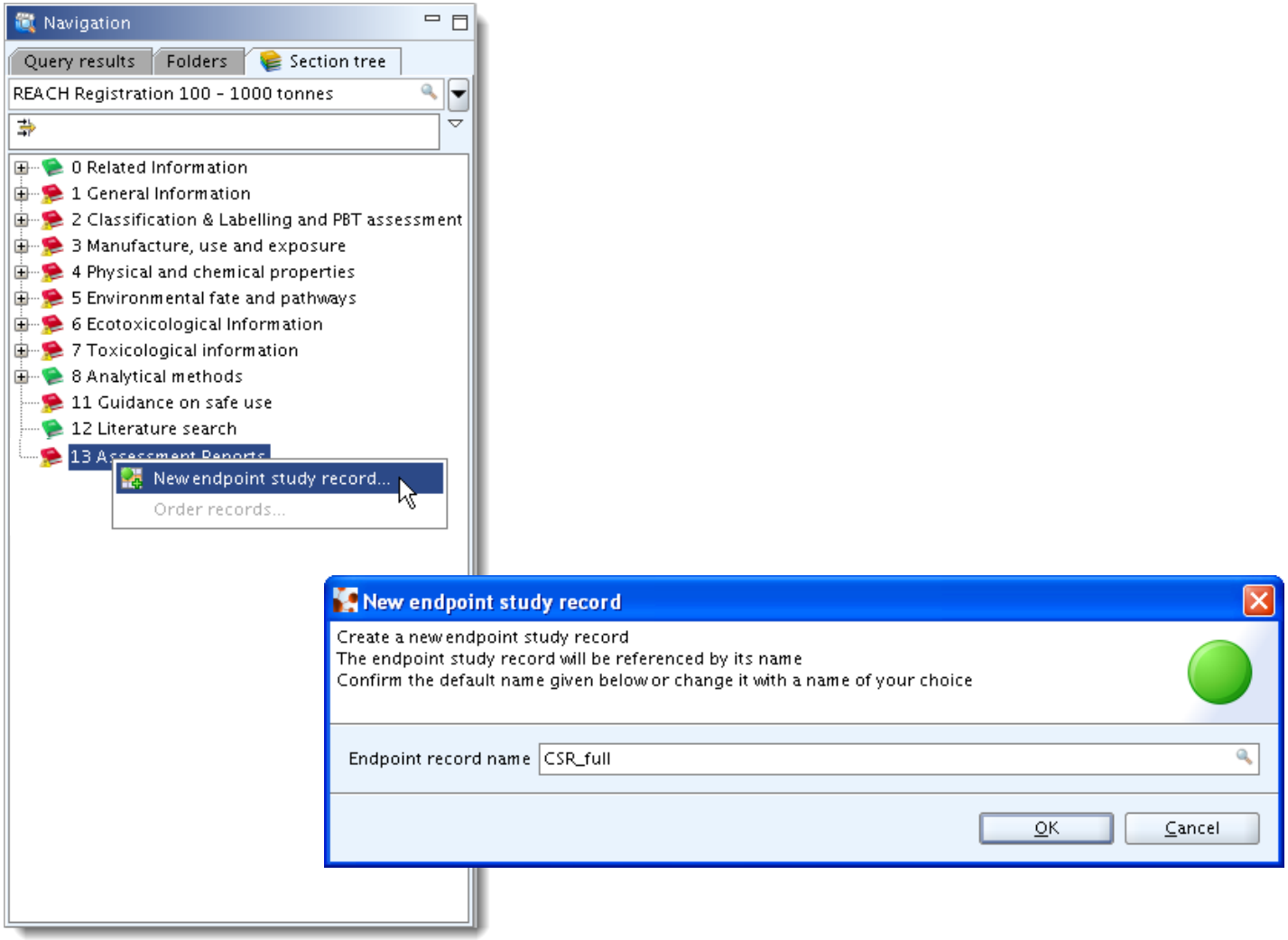
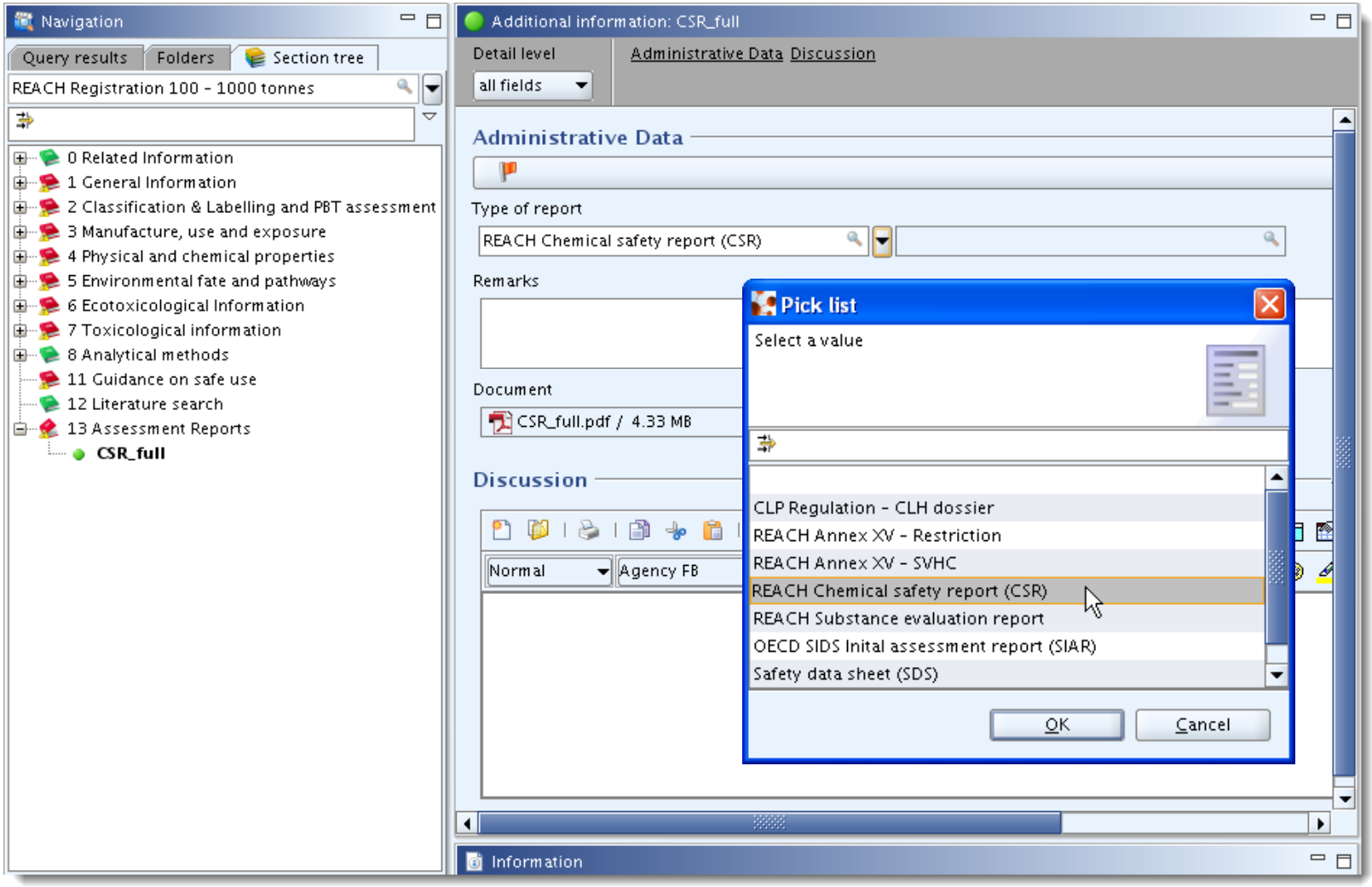
Section 13 – how to attach a Report



Section 13 – how to attach a Report



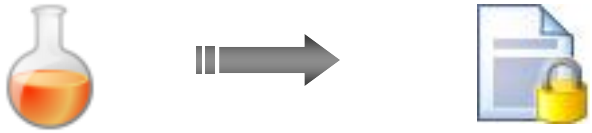
Creating and exporting a dossier

How to:

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

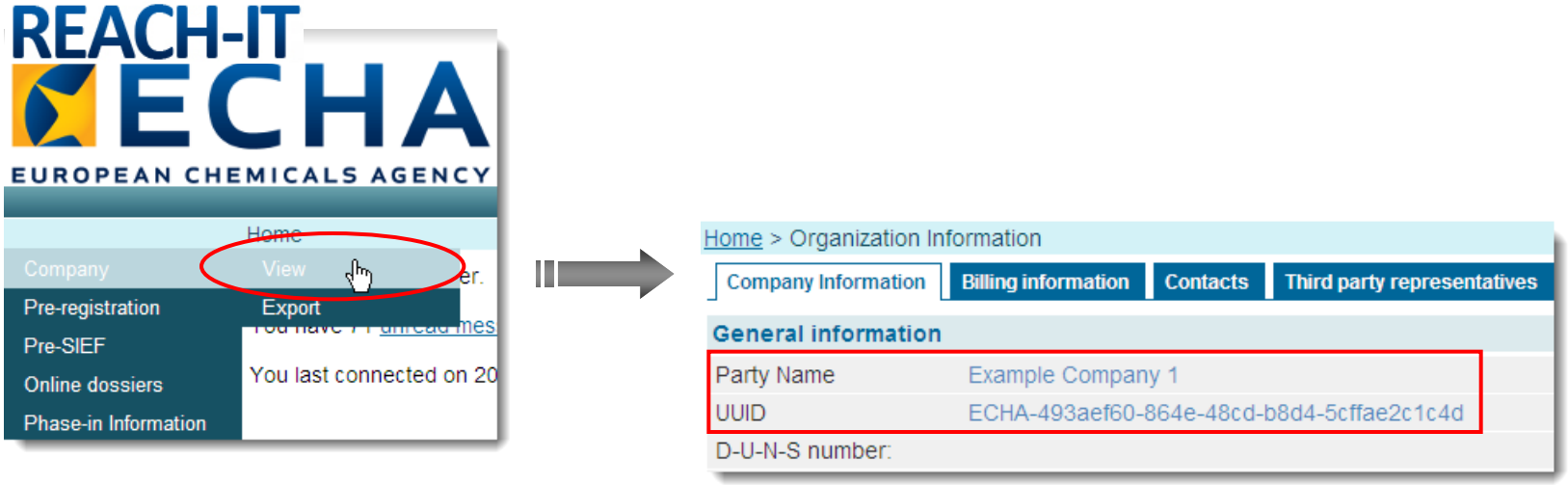
Creation of a IUCLID dossier

- Starting point is a complete Substance dataset;
  - all information required for REQUIRED TEMPLATE
- 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.



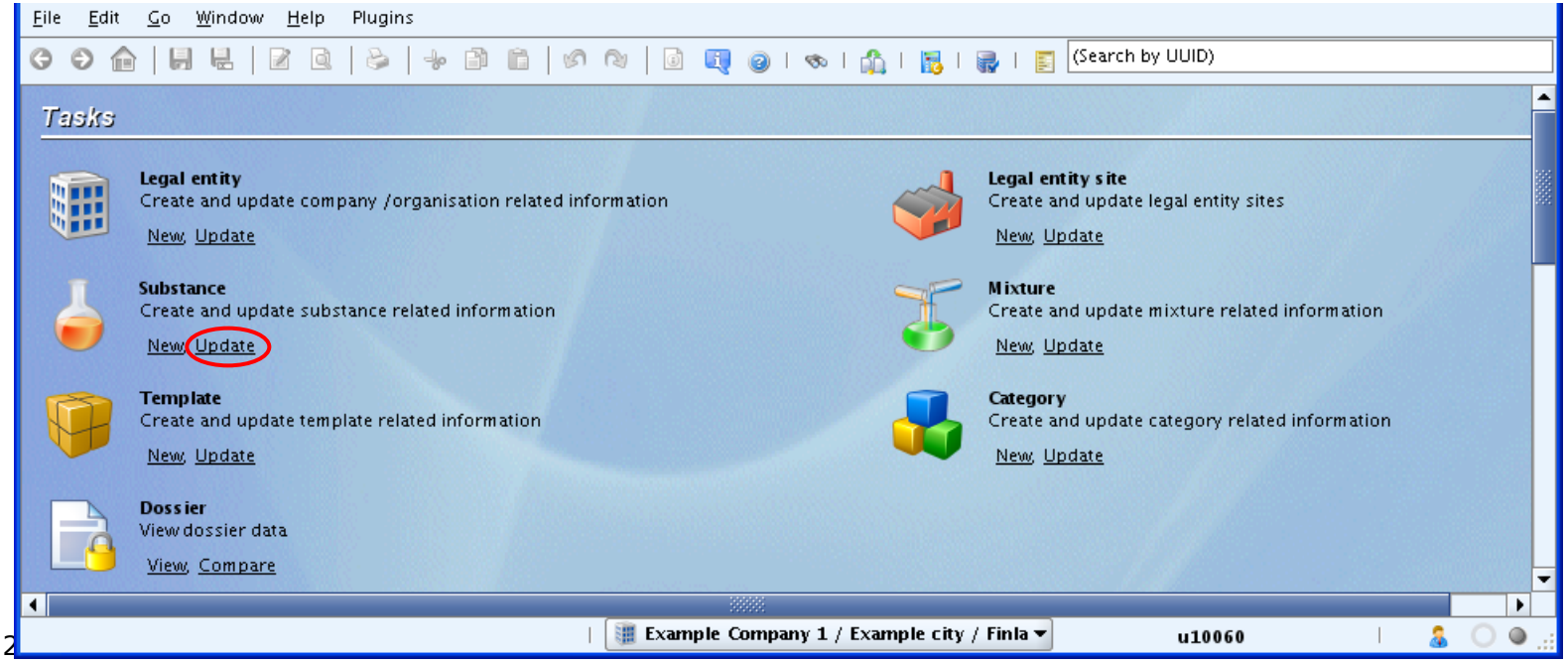
Before creating the dossier…

- 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



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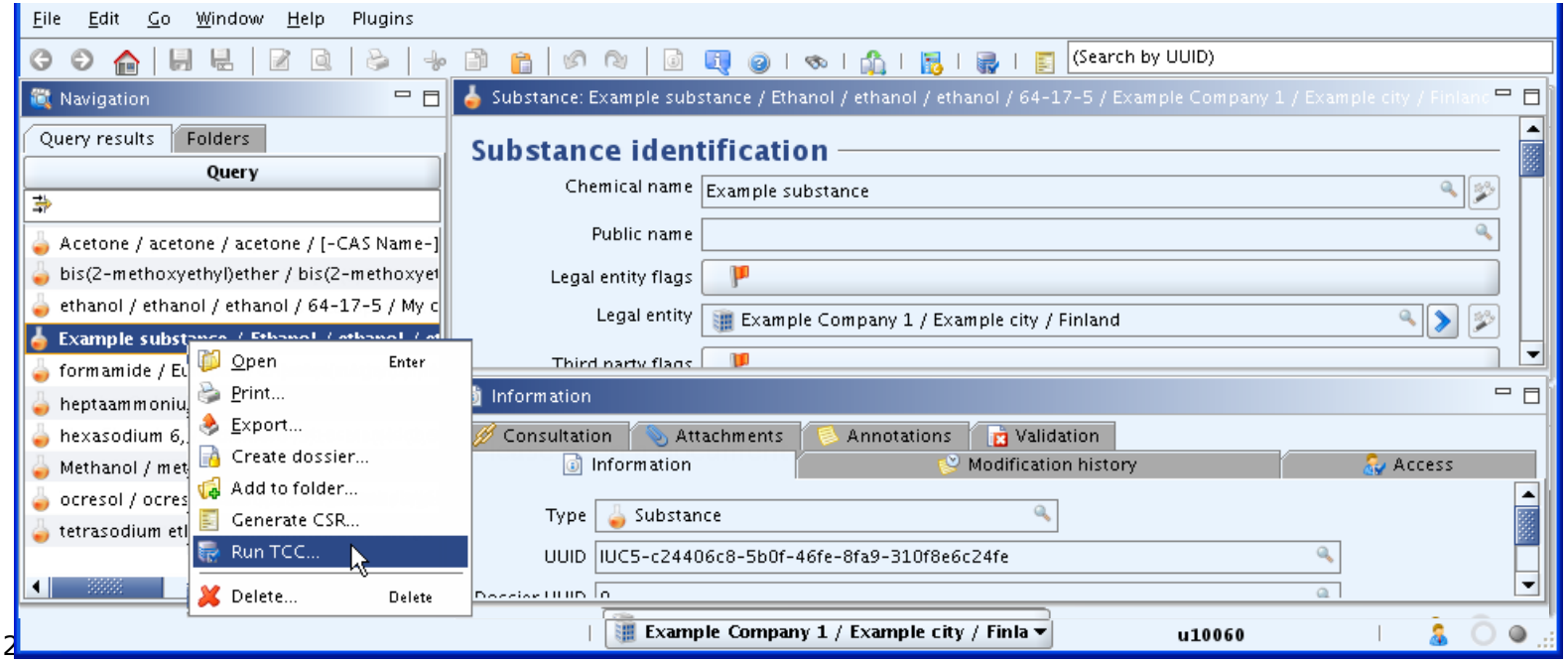

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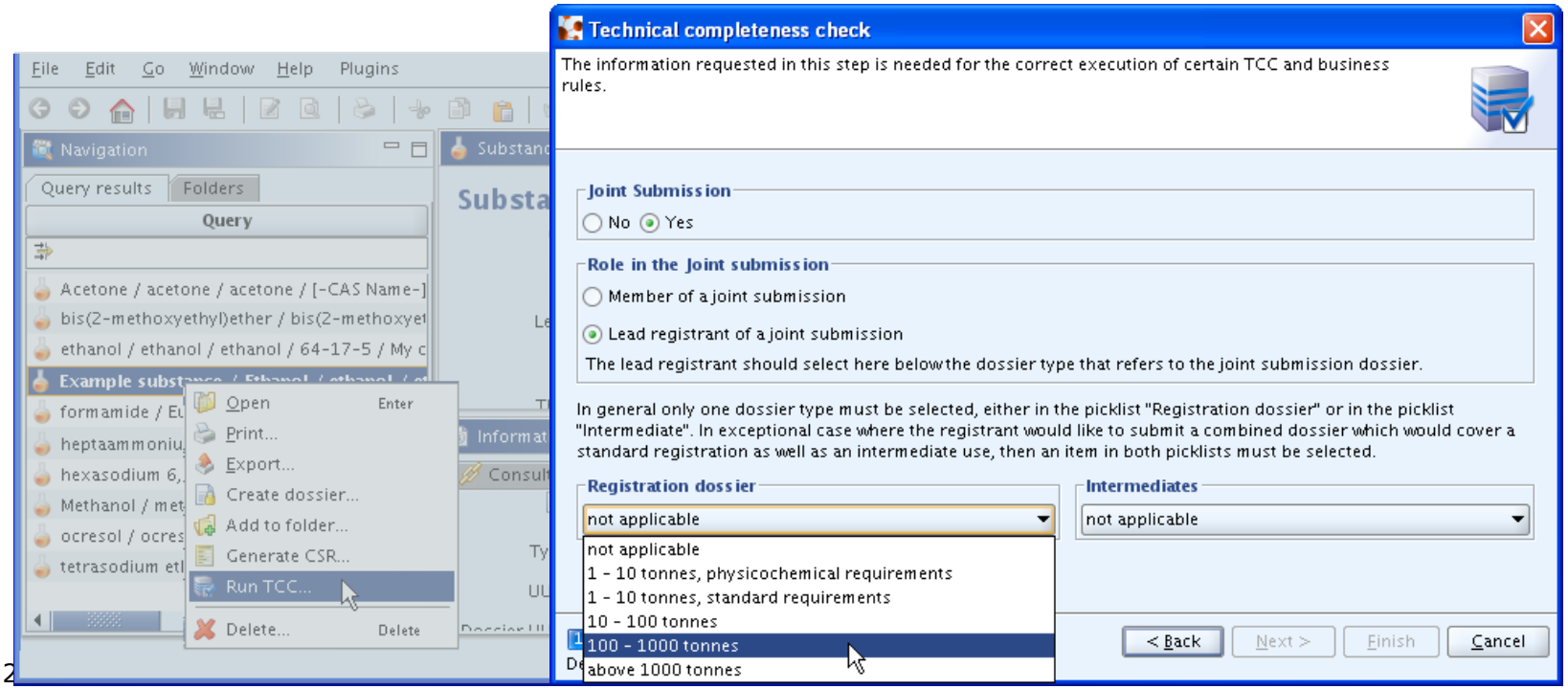

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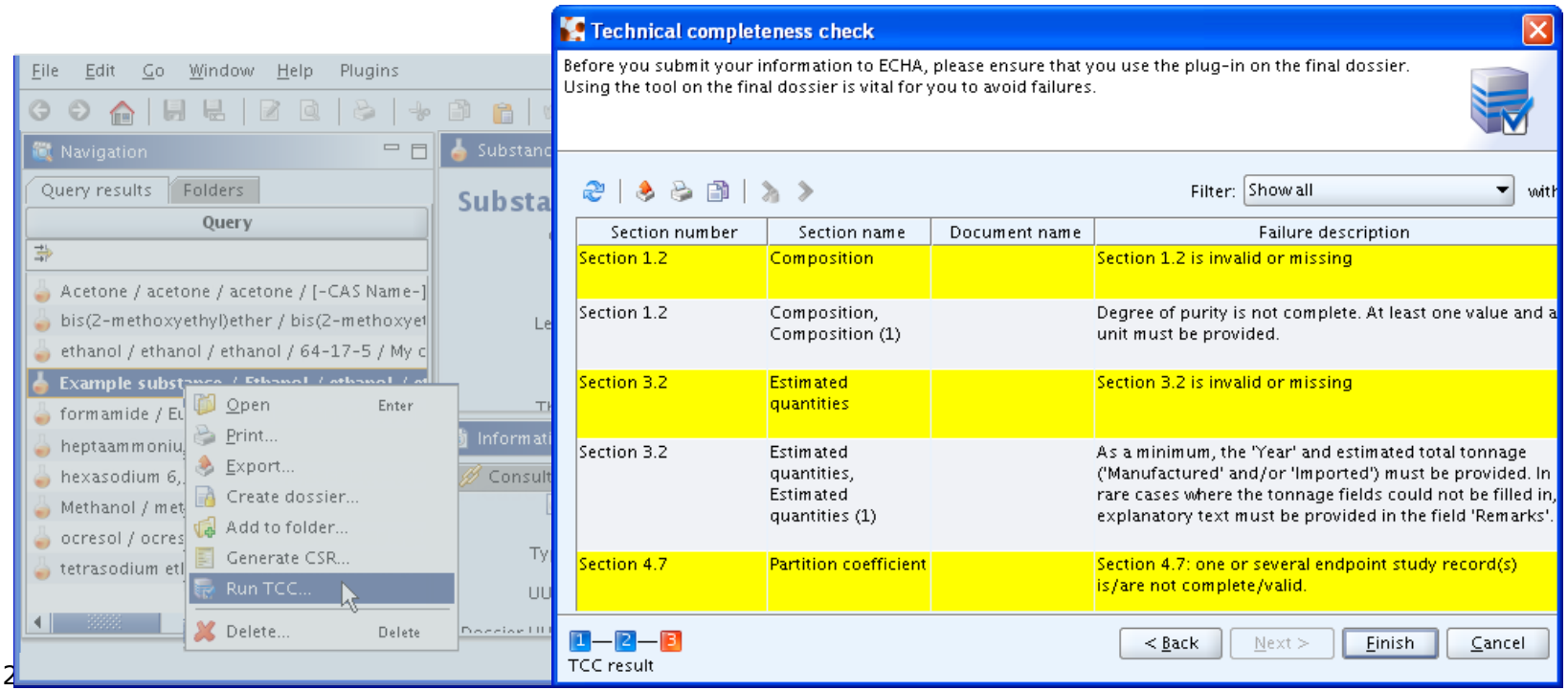
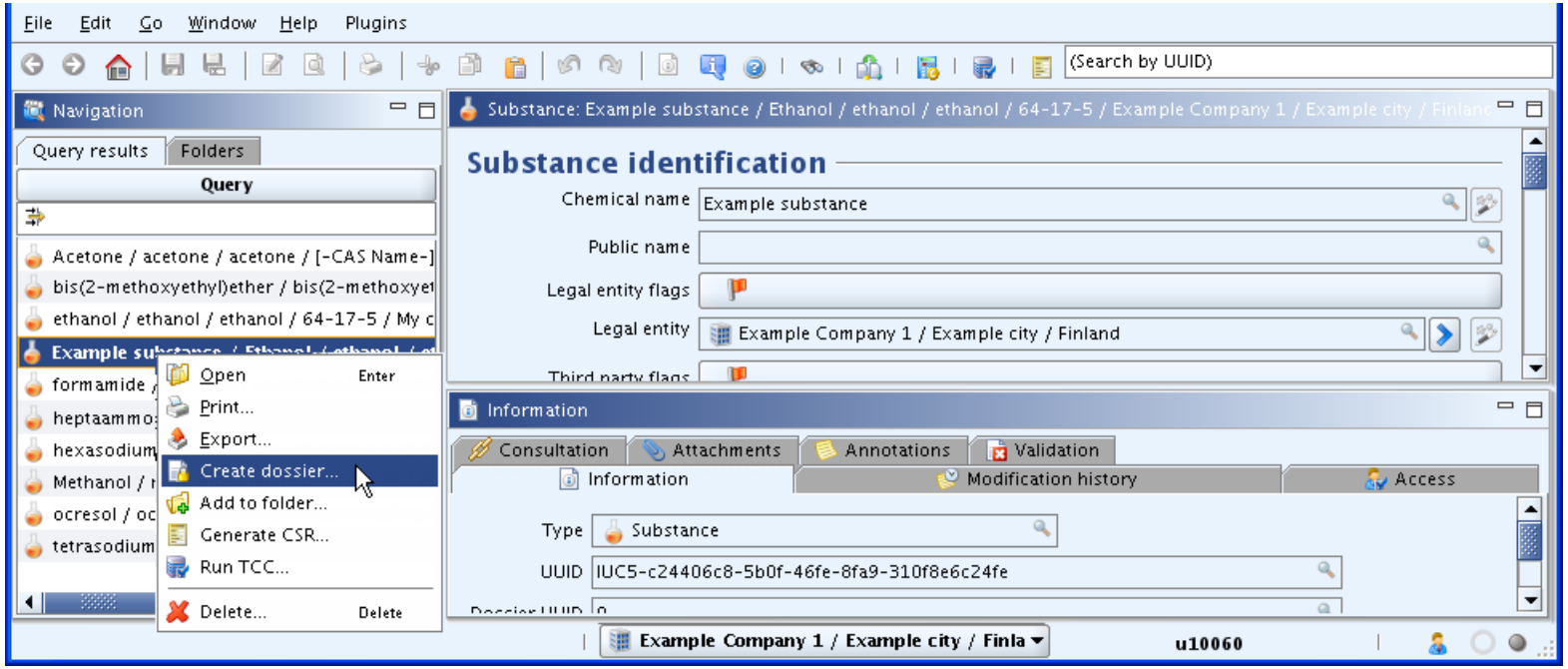


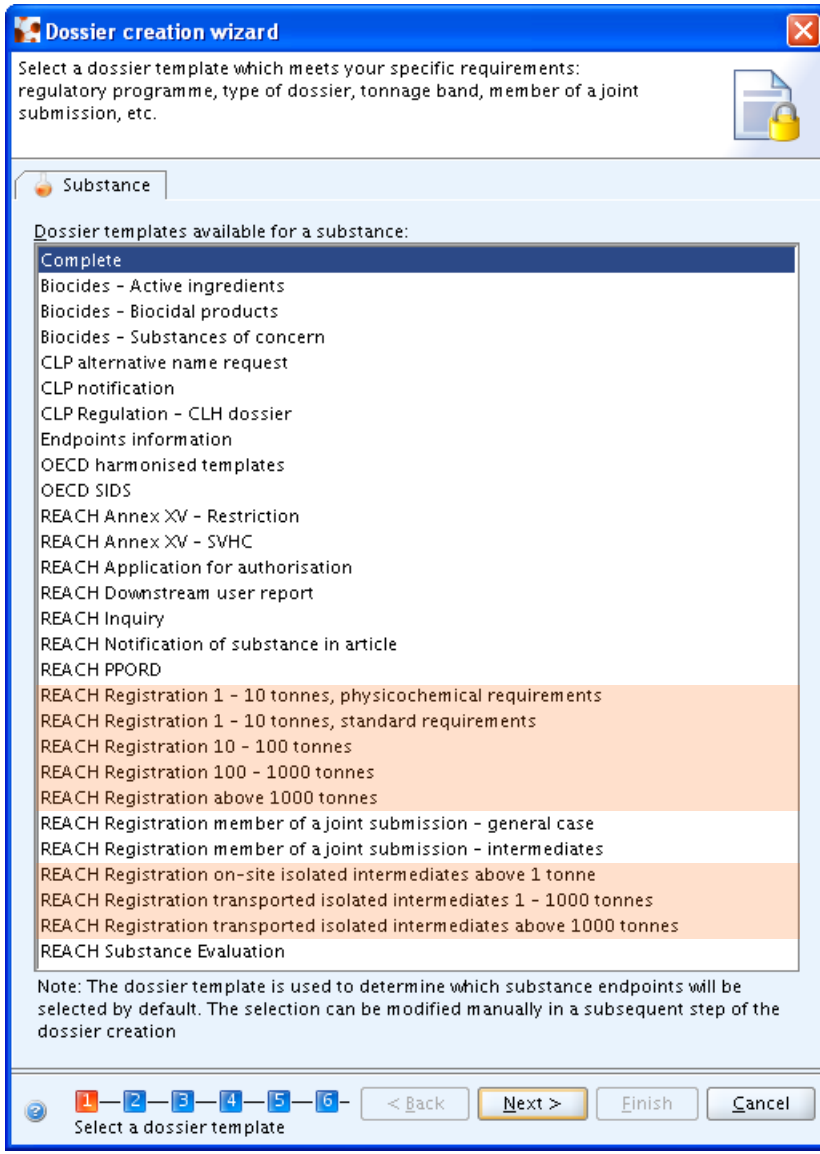
How to create a dossier

- 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!



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

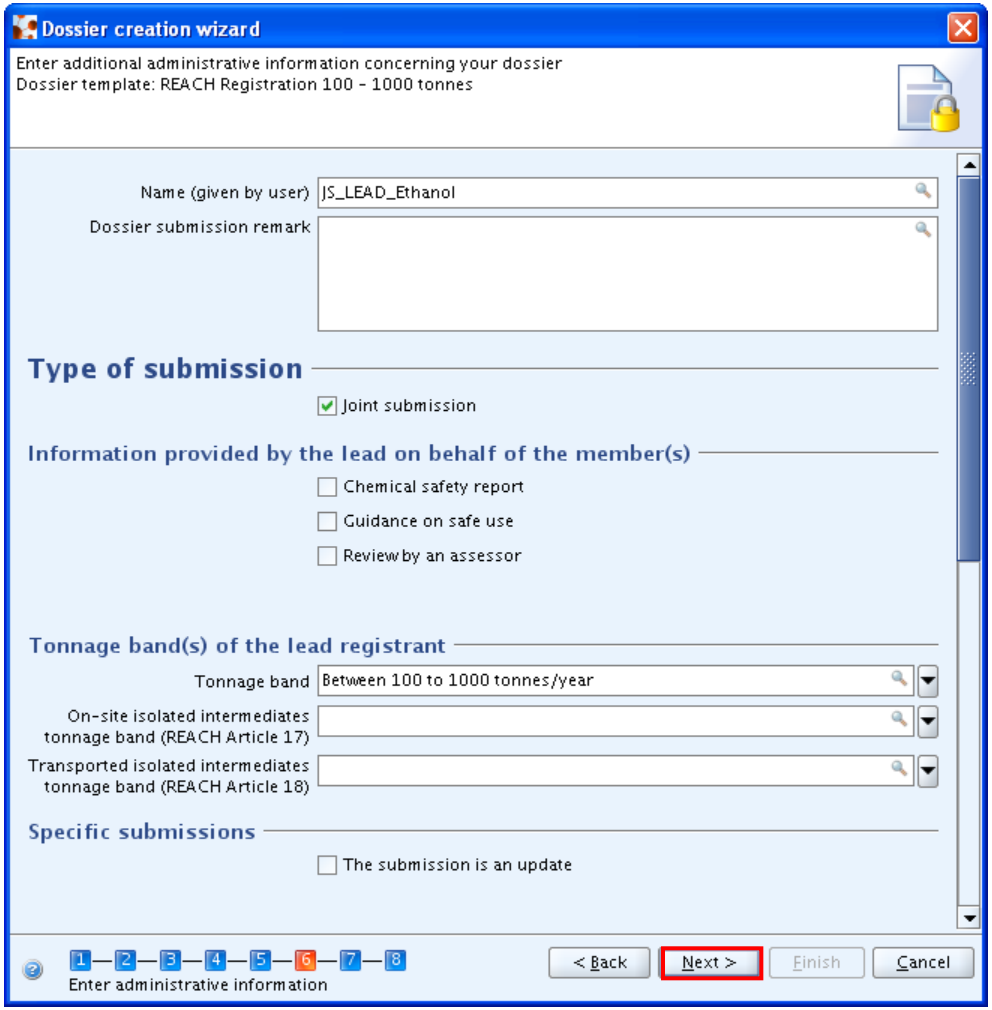
How to create a dossier

- 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")

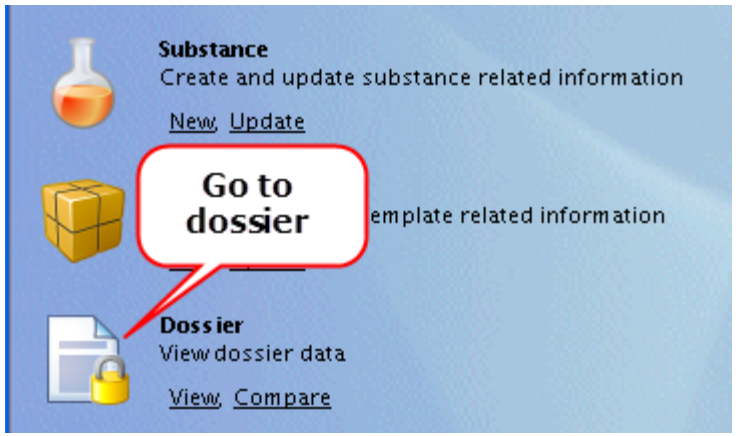
How to create a dossier

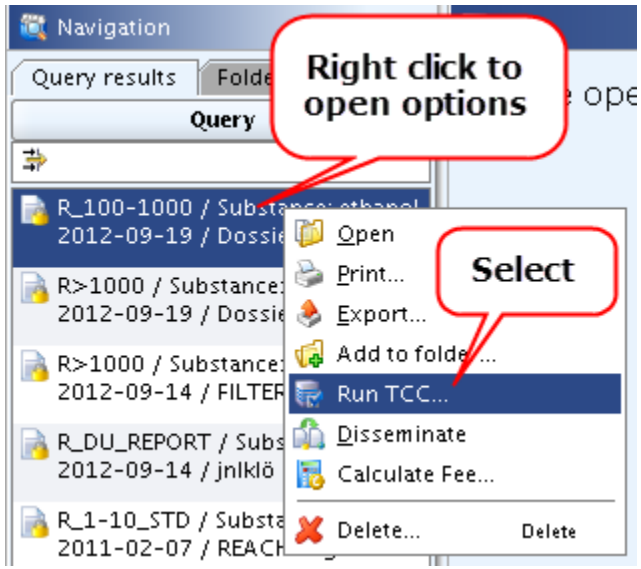
- Fill in dossier header information
- Joint submission
- Indicate here your own tonnage band
- Indicate which information you provide
- Complete dossier creation wizard



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

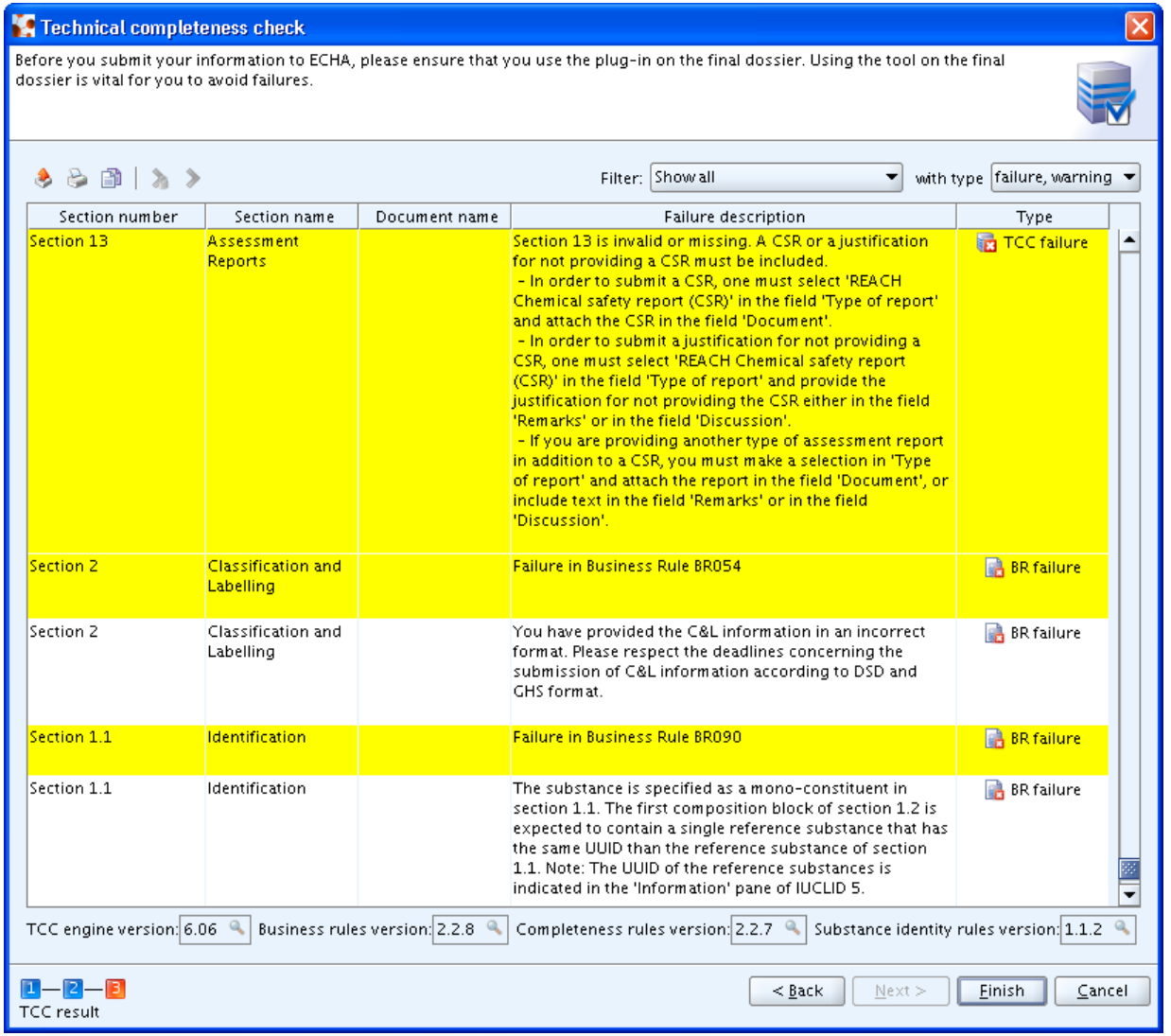
Run the TCC plug-in once more – on your dossier



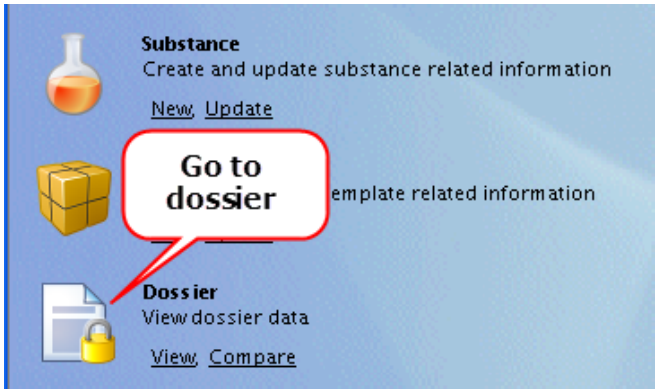


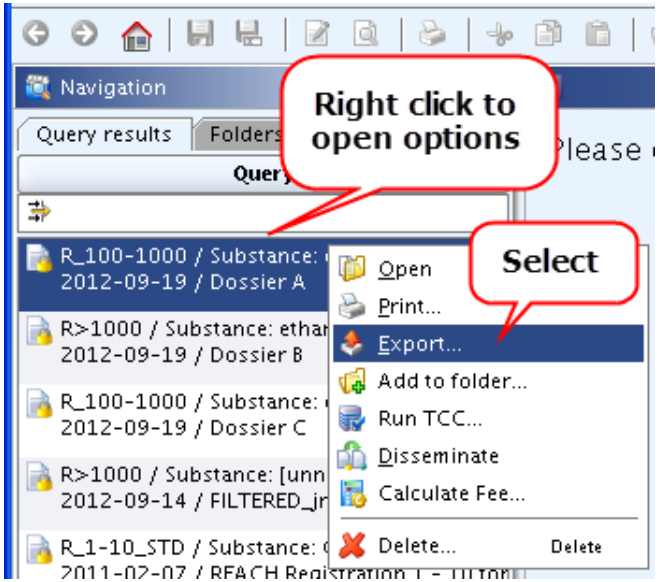
What if there are BR / TCC failures?

- Correct the missing / incomplete data in the substance dataset
- Create a dossier again
- ➢ A Dossier **cannot** be modified

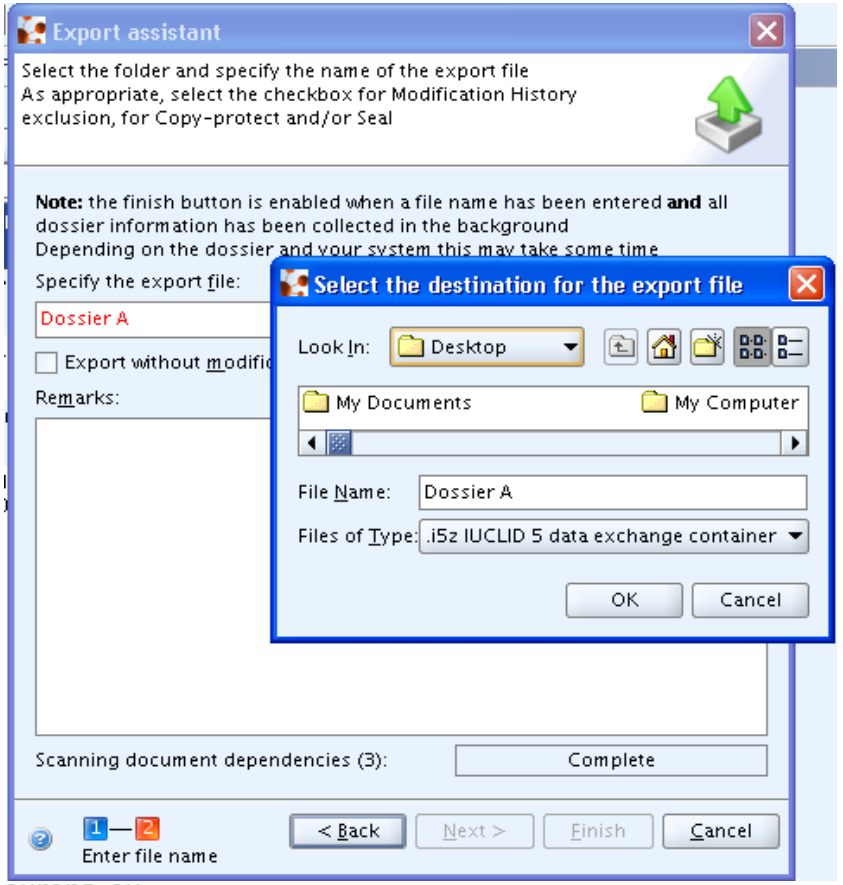


Export the dossier





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



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Thank you