

# Basic elements of IUCLID 5

## IUCLID 5.5 BASICS

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# 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

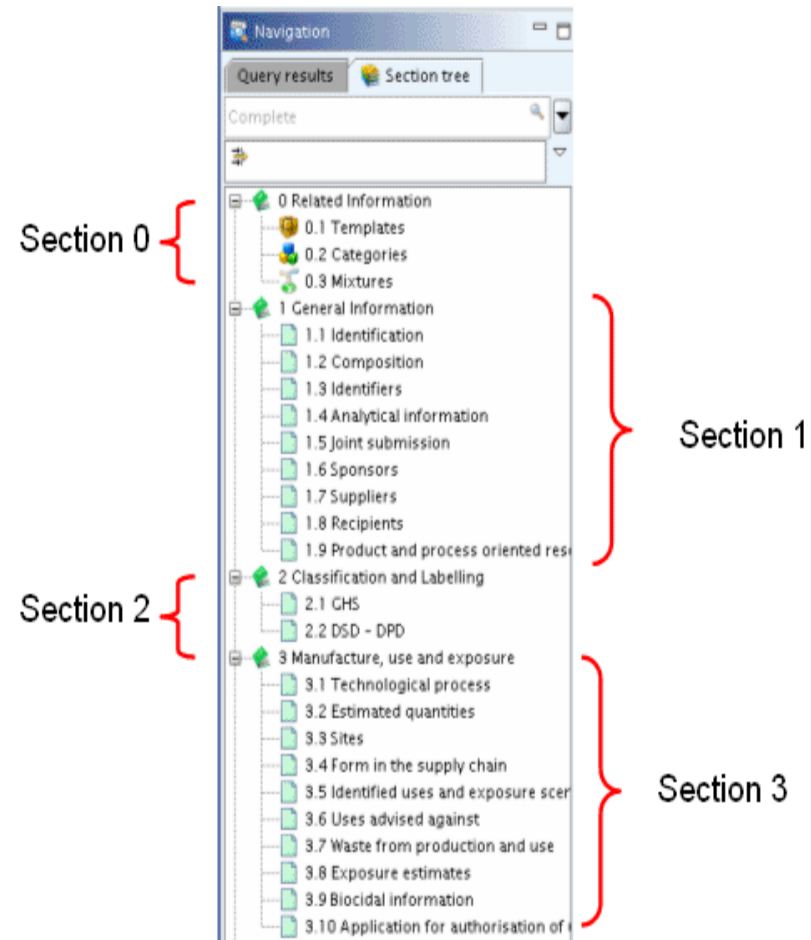
- Central core of information in IUCLID
  - It contains all data related to a chemical substance (chemical identity and all required and available endpoint study summaries)
  - Repository of data, which is used as a basis to create a registration Dossier

## 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.*



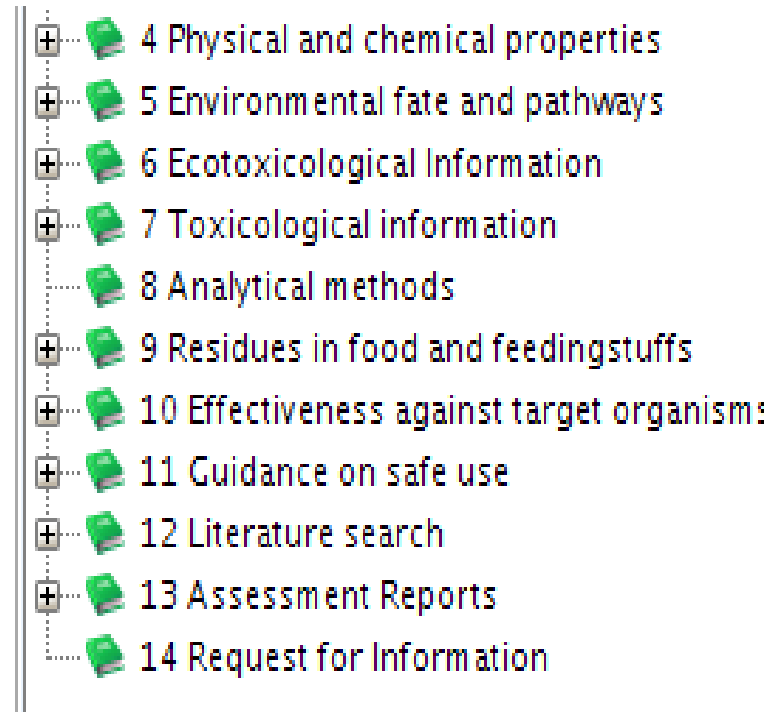
# Substance dataset, sections 4-14

## Multiple endpoint elements

- Endpoint Sections 4 - 14 are the containers for Endpoint study records and Endpoint summary records.

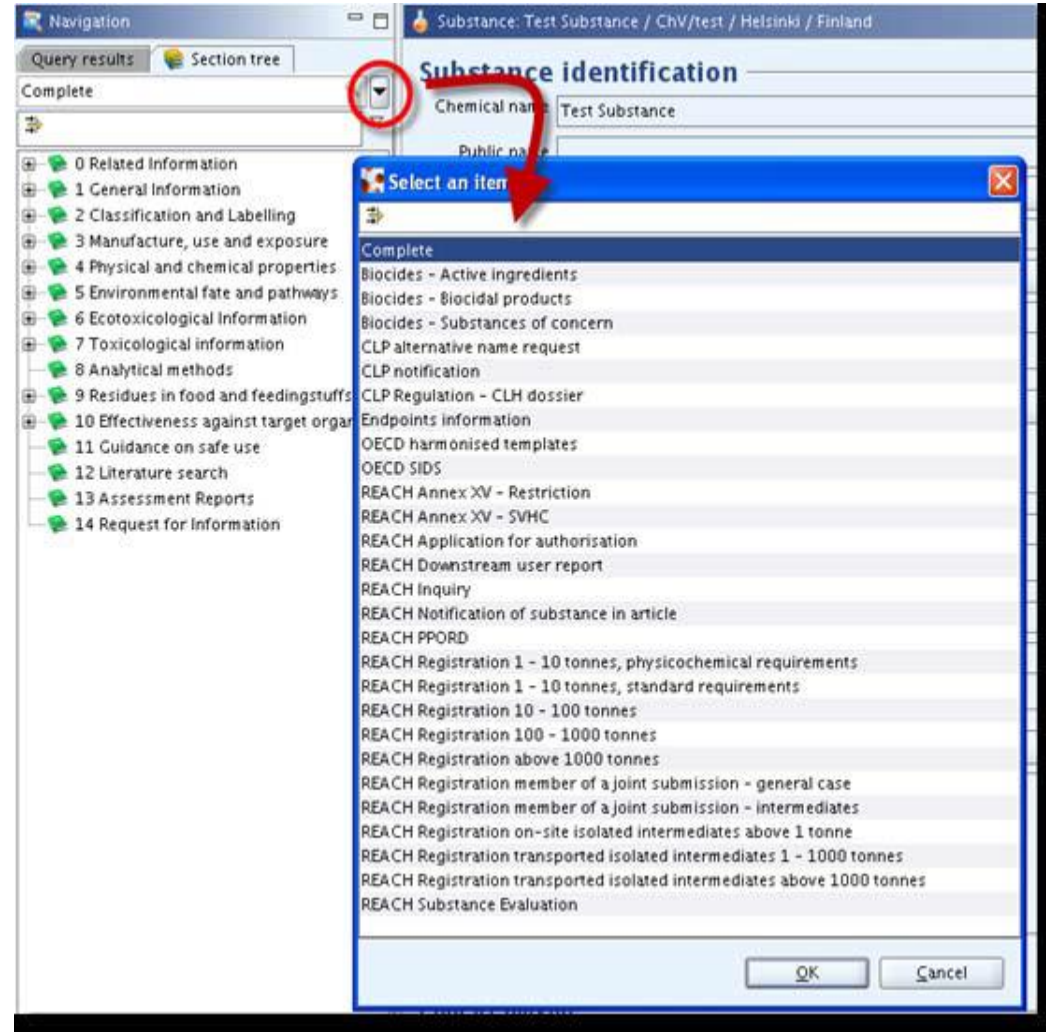
Every Endpoint record always belongs to a Substance dataset.

- Every Endpoint section can have multiple Endpoint **study** records and one Endpoint **summary**

- 
- + 4 Physical and chemical properties
  - + 5 Environmental fate and pathways
  - + 6 Ecotoxicological Information
  - + 7 Toxicological information
  - 8 Analytical methods
  - + 9 Residues in food and feedingstuffs
  - + 10 Effectiveness against target organisms
  - + 11 Guidance on safe use
  - + 12 Literature search
  - + 13 Assessment Reports
  - 14 Request for Information

# 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
- Creating and exporting a dossier

# Creation of a new Substance dataset

The screenshot displays the IUCLID 5.5.0 software interface. The main window has a menu bar (File, Edit, Go, Window, Help, Plugins) and a toolbar. The 'Tasks' section is visible, with the 'Substance' task highlighted by a red box and a red arrow pointing to the 'Substance assistant' dialog box. The 'Substance assistant' dialog box is titled 'Substance assistant' and contains the text 'Create a new substance'. It features a text input field for 'Chemical name' with the value 'Example substance' and a search icon. Below the input field are buttons for '< Back', 'Next >', 'Finish', and 'Cancel'. The dialog box also includes a small icon of a flask and a 'Set name' label with a small icon of a document.

**Tasks**

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

**Inventories**

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

**Tools and administration**

- Manage users, roles, preferences, etc.**  
[User preferences](#), [Set password](#), [Set question](#), User management, Role management
- Bulk export**  
Export multiple documents  
[Run](#)
- Import**  
Import data from other IUCLID 5 systems  
[Import](#)

# Creation of a new Substance dataset

The screenshot displays the IUCLID 5.5.0 software interface. The main window shows a sidebar with various task categories: **Tasks** (Legal entity, Substance, Template, Dossier), **Inventories** (Inventory, Reference substance), and **Tools and administration** (Manage users, Bulk export). The **Substance** task is highlighted with a red box, and a red arrow points to the **Substance assistant** dialog box.

The **Substance assistant** dialog box is titled "Create a new substance" and contains a text field for "Chemical name" with the value "Example substance". Below the text field are buttons for "< Back", "Next >", "Finish", and "Cancel". The "Next >" button is highlighted with a red box.

A second **Substance assistant** dialog box is shown below the first, titled "Set legal entity". It contains a dropdown menu for "Legal entity" with the value "Oy / Helsinki / Finland". Below the dropdown are buttons for "< Back", "Next >", "Finish", and "Cancel". The "Finish" button is highlighted with a red box.

# Creation of a new Substance dataset

The screenshot displays the IUCLID 5.5.0 software interface. The window title is "IUCLID 5.5.0 - Example substance / Oy / Helsinki / Finland". The interface includes a menu bar (File, Edit, Go, Window, Help, Plugins), a toolbar, and a search bar labeled "(Search by UUID)".

On the left, a "Navigation" pane shows a "Section tree" with categories like "0 Related Information", "1 General Information", "2 Classification & Labelling and PBT assessment", etc. The main area is titled "Substance: Example substance / Oy / Helsinki / Finland" and contains several sections:

- Substance identification:** Fields for "Chemical name" (Example substance), "Public name", "Legal entity flags" (with a flag icon), "Legal entity" (Oy / Helsinki / Finland), and "Third party flags".
- Role in the supply chain:** "Role flags" field and a "Role" section with checkboxes for "Manufacturer", "Importer", "Only representative", and "Downstream user".
- Reference substance:** "Reference substance flags" field.
- Type of substance:** "Composition" and "Origin" fields, each with a dropdown arrow.
- Other names:** A table with columns: "Flags", "Name Type", "Name", "Country", "Remarks".

At the bottom, an "Information" pane shows tabs for "Consultation", "Attachments", "Annotations", and "Validation". The status bar at the very bottom indicates "Oy / Helsinki / Finland" and "User 1".

# Creation of a new Substance dataset

The image displays two screenshots of the IUCLID 5.5.0 software interface. The left screenshot shows the main 'Tasks' menu with four categories: 'Legal entity', 'Substance', 'Template', and 'Dossier'. The 'Substance' category is highlighted, and the 'Update' link is enclosed in a red box. A red arrow points from this box to the right screenshot. The right screenshot shows the 'Substance identification' form for an example substance, with fields for 'Chemical name', 'Public name', 'Legal entry flags', 'Legal entry', 'Third party flags', 'Role in the supply chain', 'Reference substance', 'Type of substance', and 'Other names'. A navigation pane on the left of the right screenshot shows a section tree with 13 folders, including '0 Related Information', '1 General Information', '2 Classification & Labelling and PBT assessment', '3 Manufacture, use and exposure', '4 Physical and chemical properties', '5 Environmental fate and pathways', '6 Ecotoxicological information', '7 Toxicological information', '8 Analytical methods', '9 Guidance on safe use', '10 Literature search', and '11 Assessment Reports'.

# Creation of a new Substance dataset

The screenshot displays the IUCLID 5.5.0 interface for creating a new substance dataset. The main window is titled "IUCLID 5.5.0 - Example substance / Oy / Helsinki / Finland". The "Substance identification" section is active, showing fields for Chemical name, Public name, Legal entity flags, and Legal entity. A "Select an item" dialog box is open, listing various REACH registration options. A red circle highlights a dropdown arrow in the "Substance identification" section, and a red arrow points from it to the "Select an item" dialog box.

**Substance identification**

Chemical name: Example substance

Public name:

Legal entity flags:

Legal entity: Oy / Helsinki / Finland

**Select an item**

- REACH PPORD
- REACH Registration 1 - 10 tonnes, physicochemical requirements
- REACH Registration 1 - 10 tonnes, standard requirements
- REACH Registration 10 - 100 tonnes
- REACH Registration 100 - 1000 tonnes**
- REACH Registration above 1000 tonnes
- REACH Registration member of a joint submission - general case
- REACH Registration member of a joint submission - intermediates

**Type of substance**

Composition:

Origin:

**Other names**

Flags	Name Type	Name	Country	Remarks
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**Information**

Information | Modification history | Access | Consultation | Attachments | Annotations | Validation

Oy / Helsinki / Finland | User 1

# Creation of a new Substance dataset

The screenshot displays the IUCLID 5.5.0 software interface. The main window title is "IUCLID 5.5.0 - Example substance / Oy / Helsinki / Finland". The interface is divided into several panes:

- Navigation pane (left):** Shows a tree structure of data sections. The "1.1 Identification" section is expanded, showing sub-sections like 1.2 Composition, 1.3 Identifiers, 1.4 Analytical information, 1.5 Joint submission, 1.6 Sponsors, 1.7 Suppliers, and 1.8 Recipients.
- Substance identification form (right):** Contains the following fields:
  - Chemical name:** Example substance
  - Public name:** (empty)
  - Legal entity flags:** (flag icon)
  - Legal entity:** Oy / Helsinki / Finland
  - Third party flags:** (flag icon)
  - Third party:** (empty)
  - Role in the supply chain:**
    - Role flags:** (flag icon)
    - Role:**  Manufacturer  Importer  Only representative  Downstream user
  - Reference substance:**
    - Reference substance flags:** (flag icon)
    - Reference substance name field (empty)
  - Type of substance:**
    - Composition:** (dropdown menu)
    - Origin:** (dropdown menu)
  - Other names:** (empty text area)
- Information pane (bottom):** Contains tabs for Consultation, Attachments, Annotations, Validation, Information, Modification history, and Access.

The status bar at the bottom shows the current location "Oy / Helsinki / Finland" and the user "User 1".

# Creation of a new Substance dataset

**Navigation**

Query results | Folders | Section tree

Biocides - Active ingredients

- 0 Related Information
  - 0.1 Templates
  - 0.2 Categories
  - 0.3 Mixtures
- 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 assessment
  - 2.1 GHS
  - 2.2 DSD - DPD
  - 2.3 PBT assessment
- 3 Manufacture, use and exposure
  - 3.1 Technological process
  - 3.2 Estimated quantities
  - 3.3 Sites
  - 3.7 Exposure Scenarios, exposure and risk a
    - 3.7.1 Exposure scenarios and local asses
    - 3.7.2 Environmental assessment for aggr
  - 3.8 Biocidal information
- 4 Physical and chemical properties
- 5 Environmental fate and pathways
- 6 Ecotoxicological Information
- 7 Toxicological information
- 8 Analytical methods
- 9 Residues in food and feedingstuffs
- 10 Effectiveness against target organisms
  - 10.1 Effectiveness against target organisms
- 11 Guidance on safe use
- 12 Literature search
- 13 Assessment Reports

**Substance: Testhgfb / Mi entidad legal / Helsinki / Finland**

**Substance identification**

Chemical name: Testhgfb

Public name:

Legal entity flags:

Legal entity: Mi entidad legal / Helsinki / Finland

Third party flags:

Third party:

**Role in the supply chain**

Role flags:

Role:  Manufacturer  Importer  Only representative  Downstream user

**Reference substance**

Reference substance flags:

**Type of substance**

Composition:

Origin:

**Other names**

Flags	Name Type	Name	Country	Remarks

Add... Edit... Delete

**Information**

Information | Modification history | Access | Consultation | Attachments | Annotations | Validation

Type: Substance

UUID: IUC5-288e9265-1828-4e09-97d2-af35317aa2be

Dossier UUID: 0

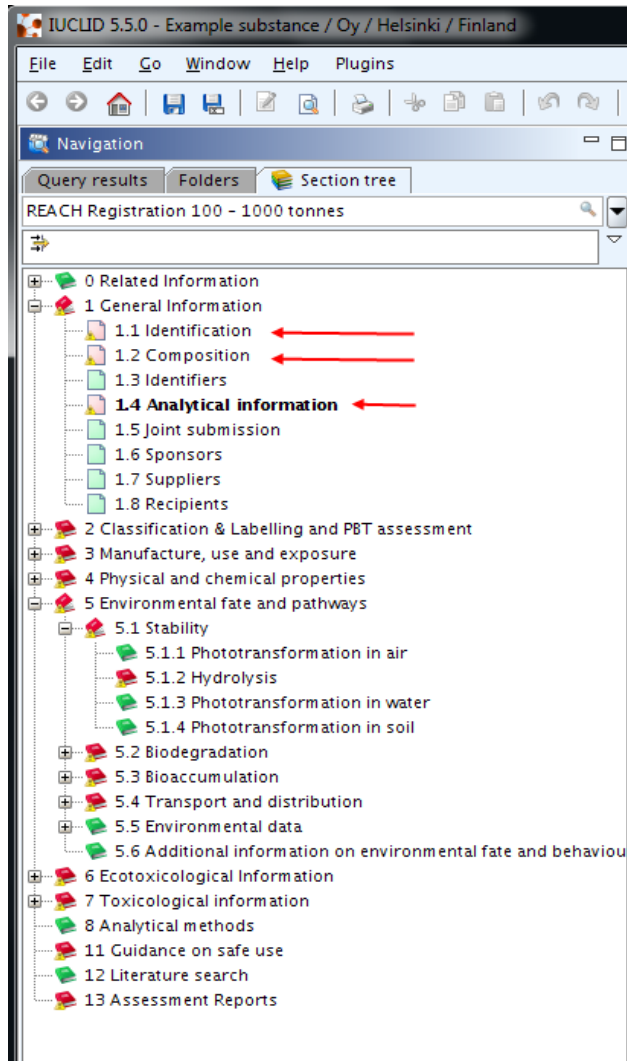
Sealed  Copy protected  Subset of original



# 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

The screenshot displays the IUCLID 5.5.0 software interface for an example substance. The window title is "IUCLID 5.5.0 - Example substance / Oy / Helsinki / Finland". The interface is divided into several panes:

- Navigation Pane (Left):** Shows a tree view of the substance's information sections. Section 1, "General Information", is expanded, and its sub-section "1.1 Identification" is highlighted with a red box.
- Main Content Area (Right):** Displays the "Substance identification" form. The "Chemical name" field is filled with "Example substance". Below it, the "Reference substance" section is highlighted with a red box. This section includes a "Reference substance flags" field and a "Type of substance" section with "Composition" and "Origin" dropdown menus. A red box highlights the edit icon (pencil) next to the "Reference substance flags" field.
- Bottom Pane:** Contains a table for "Other names" with columns for "Flags", "Name Type", "Name", "Country", and "Remarks". Below the table are tabs for "Information", "Consultation", "Attachments", "Annotations", "Validation", "Modification history", and "Access".

The status bar at the bottom indicates the user is "User 1" and the current location is "Oy / Helsinki / Finland".

# Sections 1.1 and 1.2 – Reference substance

The screenshot displays the IUCLID 5.5.0 software interface for an 'Example substance / Oy / Helsinki / Finland'. The left-hand navigation pane shows a tree structure with '1.2 Composition' highlighted in red. The main workspace is titled 'Substance composition' and contains several sections:

- Example composition:** Includes a 'Name' field (highlighted in red) containing 'Example composition', a 'Brief description' field, and a 'Composition ID' field with the value 'L-7ad3cfdd-e267-400e-8e48-7f5893c26bda'.
- Degree of purity:** Features a dropdown menu, a numerical input field with '99', another dropdown, a numerical input field with '100', and a unit dropdown set to '% (w/w)'.
- Constituents:** Shows a list with 'ca. 99.9 % (w/w)'. Below this, a 'Reference substance' field (highlighted in red) is present, along with a 'Typical concentration' field (ca., 99.9, % (w/w)), a 'Concentration range' field (>, 99, <, 100, % (w/w)), and a 'Remarks' field.

The bottom of the interface includes an 'Information' bar with tabs for 'Consultation', 'Attachments', 'Annotations', and 'Validation', and a status bar at the very bottom showing 'Oy / Helsinki / Finland' and 'User 1'.

# Linking an existing Reference substance

Query

Reference substance name

CAS number (EC inventory, CAS Information and Related CAS Information)

CAS number (EC Inventory)

EC name

EC number

CAS number

CAS name

IUPAC name





Synonyms

SMILES notation

Molecular formula

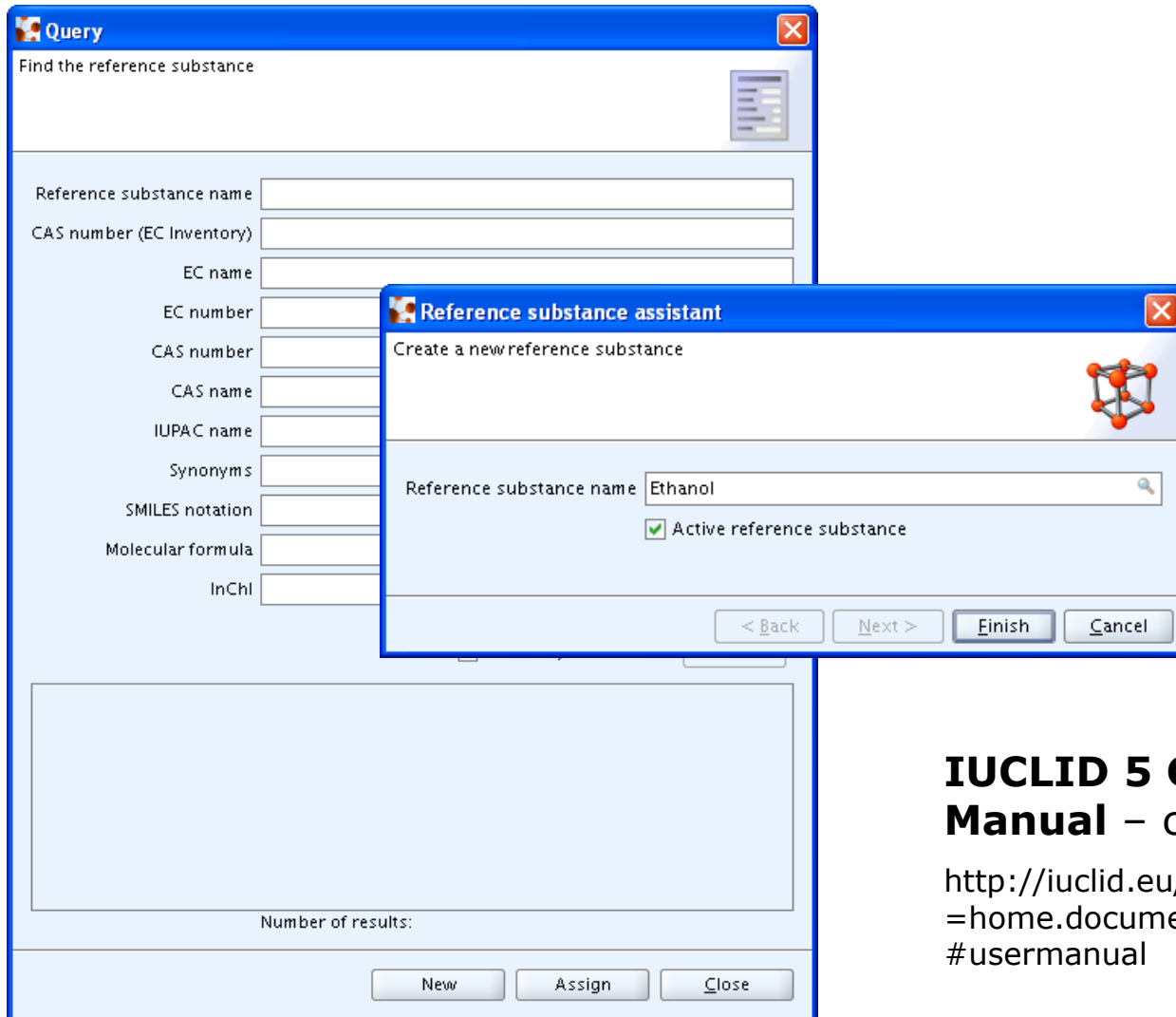
InChI

Show only active values

Name	UUID	Remarks	Last modification ...
 ethanethiol / ...	ECB5-778feb3c-9...		2007-05-10
 <b>ethanol / ethan...</b>	<b>ECB5-7d5e370b-...</b>		<b>2007-05-10</b>
 ethanediyli...	ECB5-b27380d0-...		2007-05-10
 ethane / etha...	ECB5-e0251c27-d...		2007-05-10

Number of results: 4/4

# Creating a new Reference substance



The image shows two overlapping windows from the IUCLID 5 software. The background window is titled 'Query' and contains a search interface with the text 'Find the reference substance'. It features several input fields for identifying a substance: Reference substance name, CAS number (EC Inventory), EC name, EC number, CAS number, CAS name, IUPAC name, Synonyms, SMILES notation, Molecular formula, and InChI. At the bottom of this window are buttons for 'New', 'Assign', and 'Close'. The foreground window is titled 'Reference substance assistant' and is used for creating a new reference substance. It has a search bar with 'Ethanol' entered, a checked checkbox for 'Active reference substance', and navigation buttons: '< Back', 'Next >', 'Finish', and 'Cancel'. A small molecular structure icon is visible in the top right of the assistant window.

## **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

**Navigation**

- 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 composition**

Example composition

Name: Example composition

Brief description: [ ]

Composition ID: L-7ad3cfd-d-e267-400e-8e48-7f5893c26bda

**Degree of purity**

> 99 < 100 % (w/w)

**Constituents**

ca. 99.9% (w/w) ethanol / ethanol / 64-17-5

Reference substance: ethanol / ethanol / 64-17-5

EC number	EC name
200-578-6	[ ]
CAS number	CAS name
64-17-5	[ ]
IUPAC name	ethanol

Typical concentration: ca. 99.9 % (w/w)

Concentration range: > 99 < 100 % (w/w)

Remarks: [ ]

**Impurities**

**Additives**

# How to fill in a Substance dataset

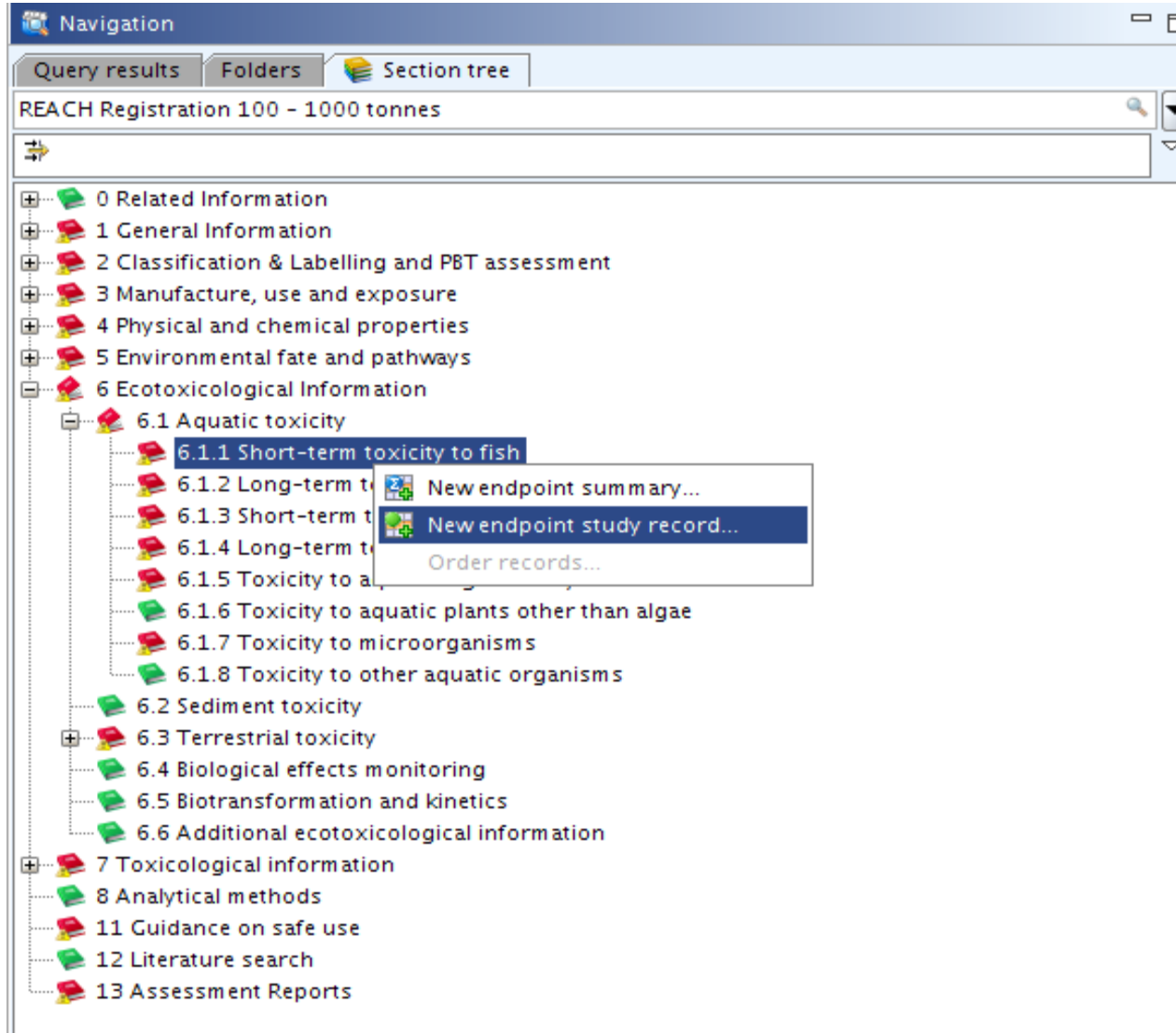
- Creation of a new Substance dataset
- Sections 1.1 and 1.2
  - Linking of a reference substance
- **Sections 4 – 7**
  - **How to create an endpoint study record**
- Section 13
  - How to attach a Report
- Creating and exporting a dossier



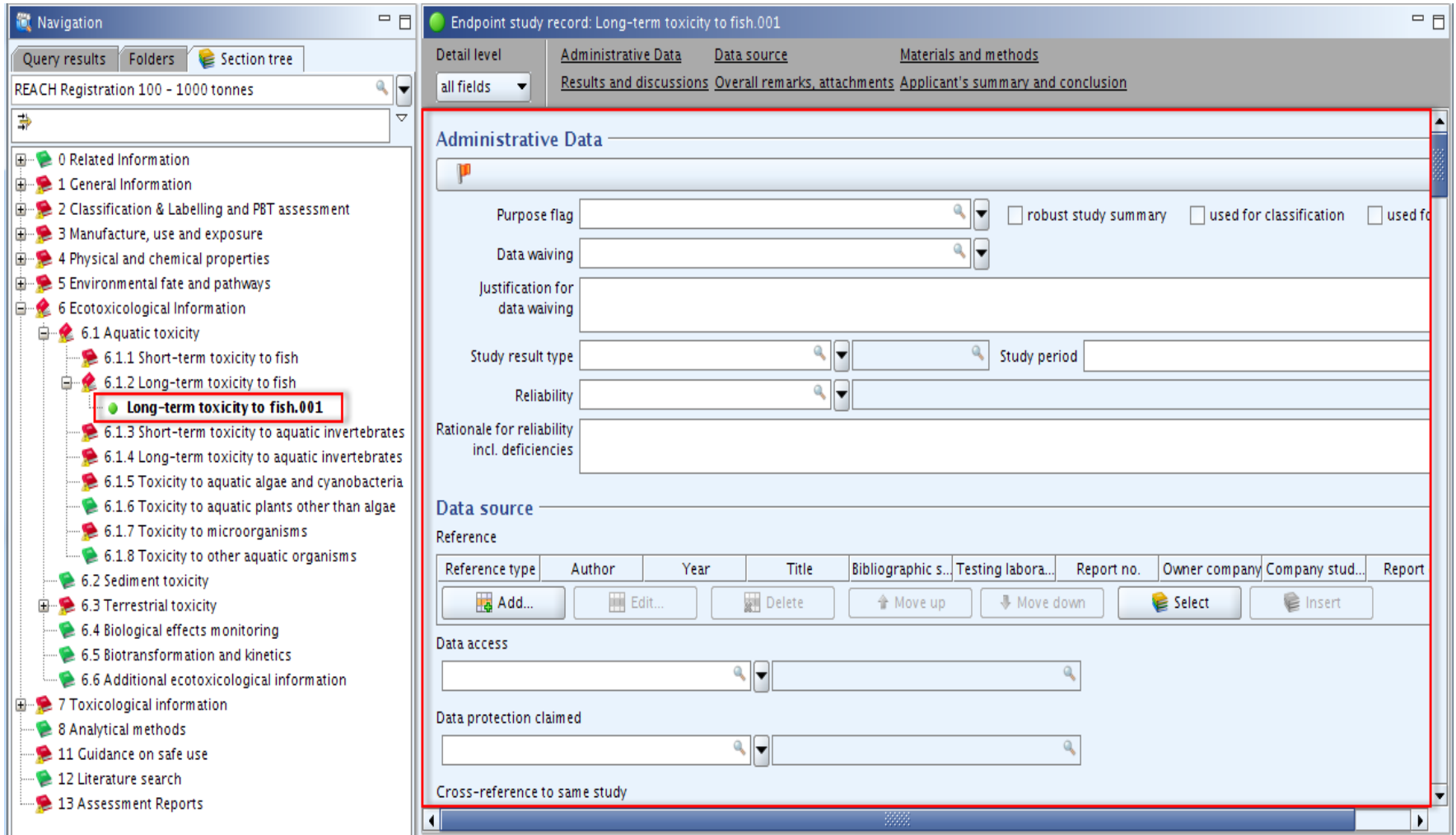
## Creation of endpoint study records

- 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



The screenshot displays the ECHA REACH registration system interface. On the left is a navigation pane showing a tree structure of registration categories. The 'Long-term toxicity to fish.001' record is highlighted in red. The main window shows the 'Endpoint study record: Long-term toxicity to fish.001' with tabs for 'Administrative Data', 'Data source', and 'Materials and methods'. The 'Administrative Data' tab is active, showing fields for Purpose flag, Data waiving, Justification for data waiving, Study result type, Reliability, and Rationale for reliability. Below this is the 'Data source' section with a 'Reference' table and 'Data access' fields. The 'Reference' table has columns for Reference type, Author, Year, Title, Bibliographic s..., Testing labora..., Report no., Owner company, Company stud..., and Report. Below the table are buttons for Add..., Edit..., Delete, Move up, Move down, Select, and Insert. The 'Data access' section has two input fields with search icons. The 'Data protection claimed' section has one input field with a search icon. The 'Cross-reference to same study' section is at the bottom.

**Navigation**

Query results | Folders | Section tree

REACH Registration 100 - 1000 tonnes

- 0 Related Information
- 1 General Information
- 2 Classification & Labelling and PBT assessment
- 3 Manufacture, use and exposure
- 4 Physical and chemical properties
- 5 Environmental fate and pathways
- 6 Ecotoxicological Information
  - 6.1 Aquatic toxicity
    - 6.1.1 Short-term toxicity to fish
    - 6.1.2 Long-term toxicity to fish
      - Long-term toxicity to fish.001**
    - 6.1.3 Short-term toxicity to aquatic invertebrates
    - 6.1.4 Long-term toxicity to aquatic invertebrates
    - 6.1.5 Toxicity to aquatic algae and cyanobacteria
    - 6.1.6 Toxicity to aquatic plants other than algae
    - 6.1.7 Toxicity to microorganisms
    - 6.1.8 Toxicity to other aquatic organisms
  - 6.2 Sediment toxicity
  - 6.3 Terrestrial toxicity
  - 6.4 Biological effects monitoring
  - 6.5 Biotransformation and kinetics
  - 6.6 Additional ecotoxicological information
- 7 Toxicological information
- 8 Analytical methods
- 11 Guidance on safe use
- 12 Literature search
- 13 Assessment Reports

**Endpoint study record: Long-term toxicity to fish.001**

Detail level: all fields

Administrative Data | Data source | Materials and methods

Results and discussions | Overall remarks, attachments | Applicant's summary and conclusion

**Administrative Data**

Purpose flag [dropdown]  robust study summary  used for classification  used for

Data waiving [dropdown]

Justification for data waiving [text area]

Study result type [dropdown] [dropdown] Study period [text area]

Reliability [dropdown]

Rationale for reliability incl. deficiencies [text area]

**Data source**

Reference

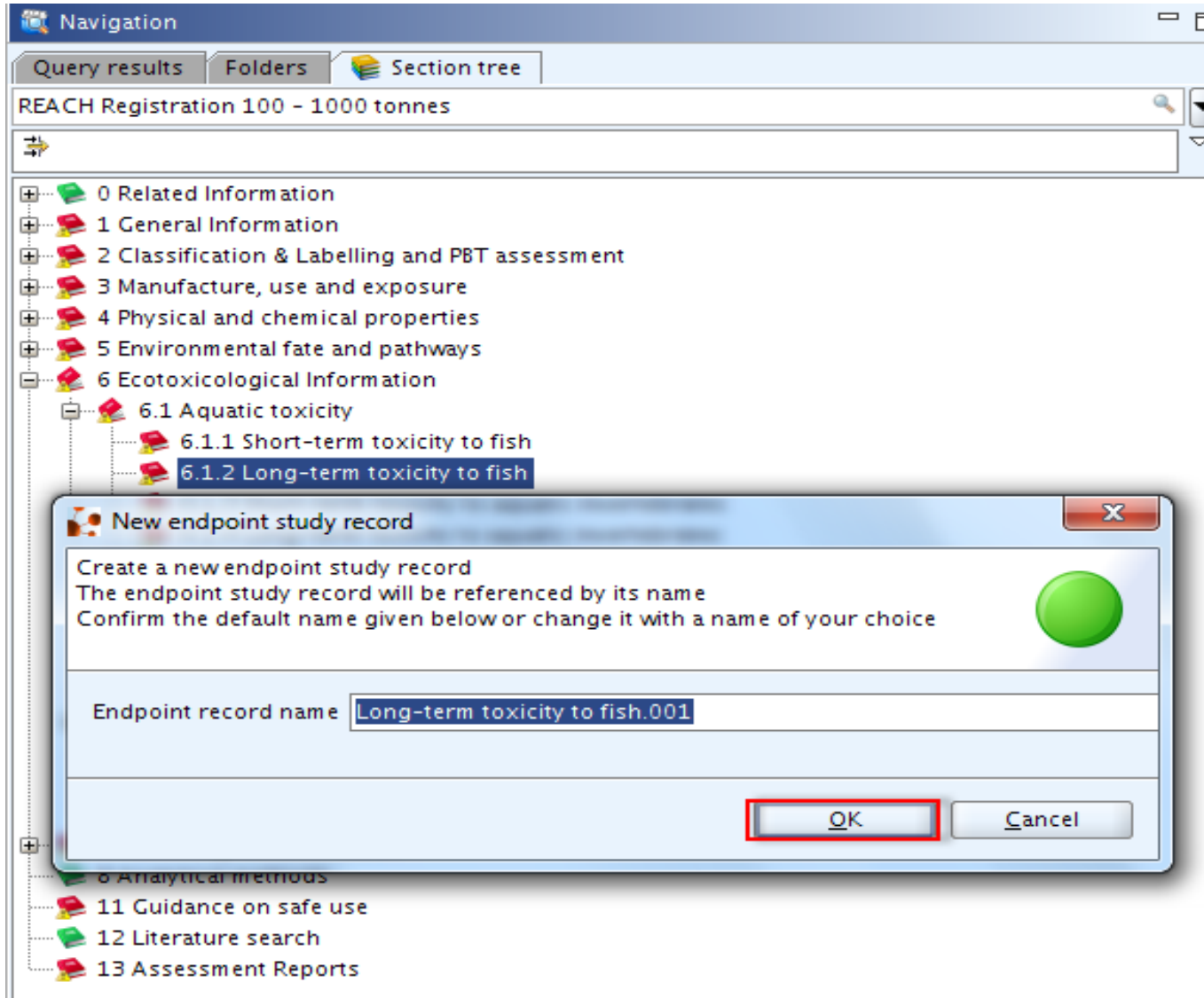
Reference type	Author	Year	Title	Bibliographic s...	Testing labora...	Report no.	Owner company	Company stud...	Report
[Add...]	[Edit...]	[Delete]	[Move up]	[Move down]	[Select]	[Insert]			

Data access [dropdown] [dropdown]

Data protection claimed [dropdown]

Cross-reference to same study [text area]

# Creation of endpoint study records



The screenshot shows a software interface with a navigation pane on the left and a main content area. The navigation pane is titled "Navigation" and has three tabs: "Query results", "Folders", and "Section tree". The "Section tree" tab is active, showing a hierarchical list of folders. The folders are numbered 0 through 13. Folder 6, "Ecotoxicological Information", is expanded to show sub-folders 6.1 "Aquatic toxicity" and 6.1.2 "Long-term toxicity to fish". The "Long-term toxicity to fish" folder is selected. A dialog box titled "New endpoint study record" is open in the foreground. The dialog box contains the following text: "Create a new endpoint study record", "The endpoint study record will be referenced by its name", and "Confirm the default name given below or change it with a name of your choice". Below the text is a text input field with the text "Long-term toxicity to fish.001". At the bottom of the dialog box are two buttons: "OK" and "Cancel". The "OK" button is highlighted with a red rectangle.

Navigation

Query results | Folders | Section tree

REACH Registration 100 - 1000 tonnes

- 0 Related Information
- 1 General Information
- 2 Classification & Labelling and PBT assessment
- 3 Manufacture, use and exposure
- 4 Physical and chemical properties
- 5 Environmental fate and pathways
- 6 Ecotoxicological Information
  - 6.1 Aquatic toxicity
    - 6.1.1 Short-term toxicity to fish
    - 6.1.2 Long-term toxicity to fish
- 6 Analytical methods
- 11 Guidance on safe use
- 12 Literature search
- 13 Assessment Reports

New endpoint study record

Create a new endpoint study record  
The endpoint study record will be referenced by its name  
Confirm the default name given below or change it with a name of your choice

Endpoint record name: Long-term toxicity to fish.001

OK Cancel

# Creation of endpoint study records

The screenshot displays the ECHA REACH registration interface. At the top, there is a navigation bar with tabs for 'Query results', 'Folders', and 'Section tree'. Below this, a search bar contains the text 'REACH Registration 100 - 1000 tonnes'. The main area shows a hierarchical tree structure of registration sections. The '6 Ecotoxicological Information' section is expanded, showing sub-sections 6.1 through 6.6. Under 6.1 'Aquatic toxicity', sub-section 6.1.2 'Long-term toxicity to fish' is selected and highlighted in blue. A dialog box titled 'Endpoint study record' is overlaid on the tree. The dialog contains a molecular structure icon and the text: 'Save current item with the created endpoint study record? Please note: changes are irreversible'. At the bottom of the dialog are 'Save' and 'Cancel' buttons.

Navigation

Query results Folders Section tree

REACH Registration 100 - 1000 tonnes

- 0 Related Information
- 1 General Information
- 2 Classification & Labelling and PBT assessment
- 3 Manufacture, use and exposure
- 4 Physical and chemical properties
- 5 Environmental fate and pathways
- 6 Ecotoxicological Information
  - 6.1 Aquatic toxicity
    - 6.1.1 Short-term toxicity to fish
    - 6.1.2 Long-term toxicity to fish
    - 6.1.3 Short-term toxicity to aquatic invertebrates
    - 6.1.4
    - 6.1.5
    - 6.1.6
    - 6.1.7
    - 6.1.8
  - 6.2 Sedin
  - 6.3 Terre
  - 6.4 Biolo
  - 6.5 Biotr
  - 6.6 Additional ecotoxicological information
- 7 Toxicological information
- 8 Analytical methods
- 11 Guidance on safe use
- 12 Literature search
- 13 Assessment Reports

Endpoint study record

Save current item with the created endpoint study record?  
Please note: changes are irreversible

Save Cancel

# 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

# Section 13 – how to attach a Report

The image shows a software interface for REACH registration. The main window is titled 'Navigation' and has tabs for 'Query results', 'Folders', and 'Section tree'. The 'Section tree' tab is active, showing a list of sections for 'REACH Registration 100 - 1000 tonnes'. The sections are numbered 0 through 13. Section 13, 'Assessment Reports', is highlighted, and a context menu is open over it with the option 'New endpoint study record...' selected. A dialog box titled 'New endpoint study record' is overlaid on the bottom right. It contains the following text: 'Create a new endpoint study record. The endpoint study record will be referenced by its name. Confirm the default name given below or change it with a name of your choice.' Below the text is a text input field labeled 'Endpoint record name' with the value 'CSR\_full'. At the bottom right of the dialog are 'OK' and 'Cancel' buttons.

# Section 13 – how to attach a Report

The screenshot displays the ECHA software interface for managing registration dossiers. On the left, a 'Navigation' pane shows a tree structure of dossier sections, with '13 Assessment Reports' selected and 'CSR\_full' highlighted. The main window, titled 'Additional information: CSR\_full', shows the 'Administrative Data' section. The 'Type of report' field is set to 'REACH Chemical safety report (CSR)'. A 'Pick list' dialog box is open over the 'Remarks' field, listing various report types. The 'REACH Chemical safety report (CSR)' option is selected in the list. The 'Document' field shows 'CSR\_full.pdf / 4.33 MB' is attached. The 'Discussion' section is visible below, with a 'Normal' style and 'Agency FB' text.

Navigation

Query results Folders Section tree

REACH Registration 100 - 1000 tonnes

- 0 Related Information
- 1 General Information
- 2 Classification & Labelling and PBT assessment
- 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
  - CSR\_full

Additional information: CSR\_full

Detail level Administrative Data Discussion

all fields

Administrative Data

Type of report

REACH Chemical safety report (CSR)

Remarks

Document

CSR\_full.pdf / 4.33 MB

Discussion

Normal Agency FB

Pick list

Select a value

- CLP Regulation - CLH dossier
- REACH Annex XV - Restriction
- REACH Annex XV - SVHC
- REACH Chemical safety report (CSR)
- REACH Substance evaluation report
- OECD SIDS Initial assessment report (SIAR)
- Safety data sheet (SDS)

OK Cancel



# Creating and exporting a dossier

How to:

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



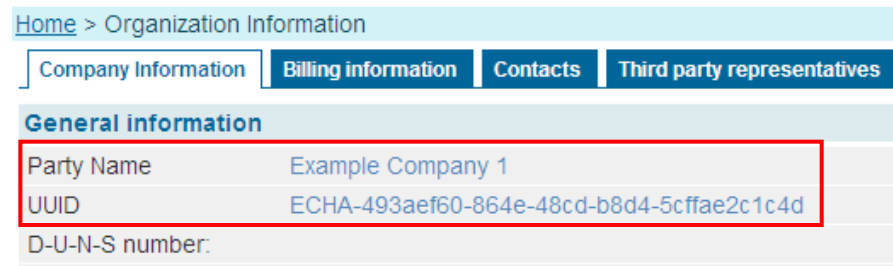
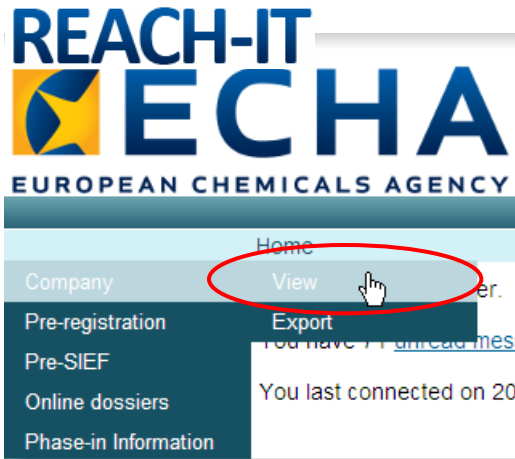
## Creation of a IUCLID dossier

- 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.



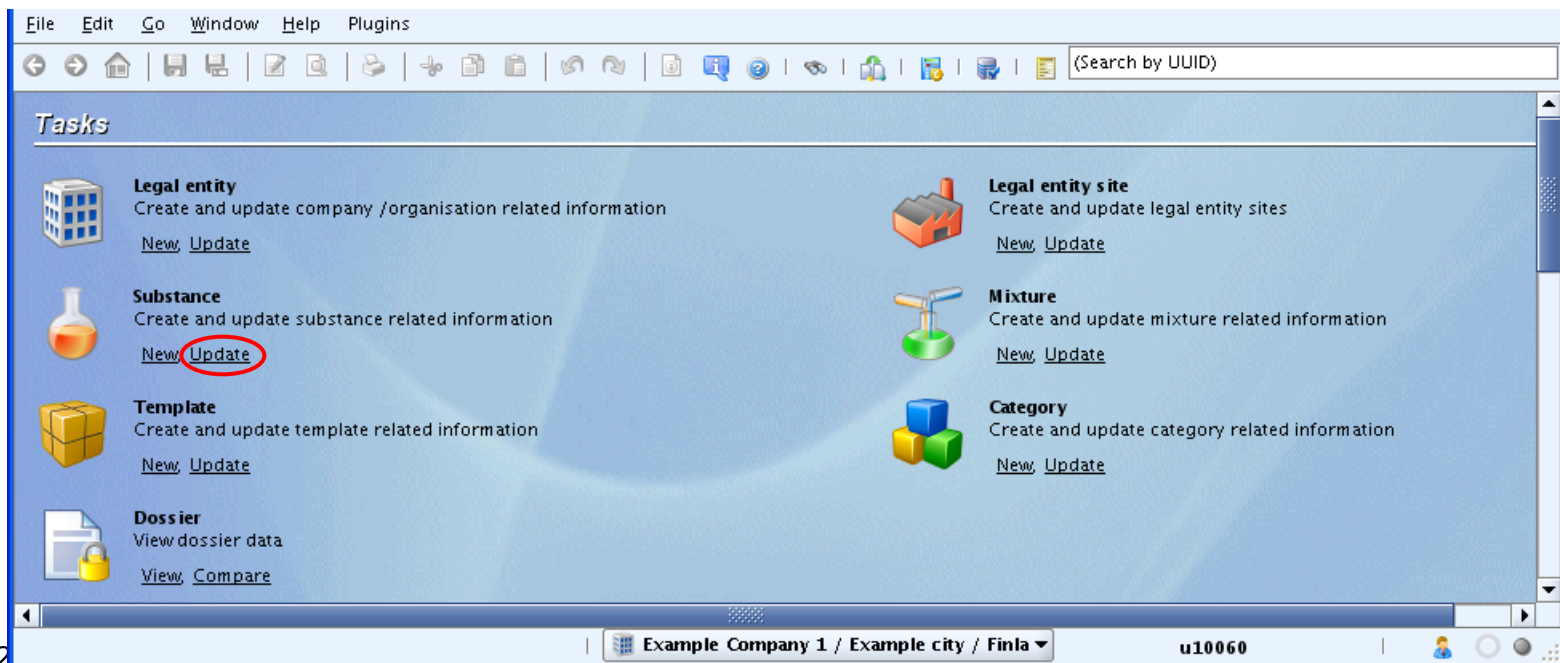
## Before creating the dossier...

- 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



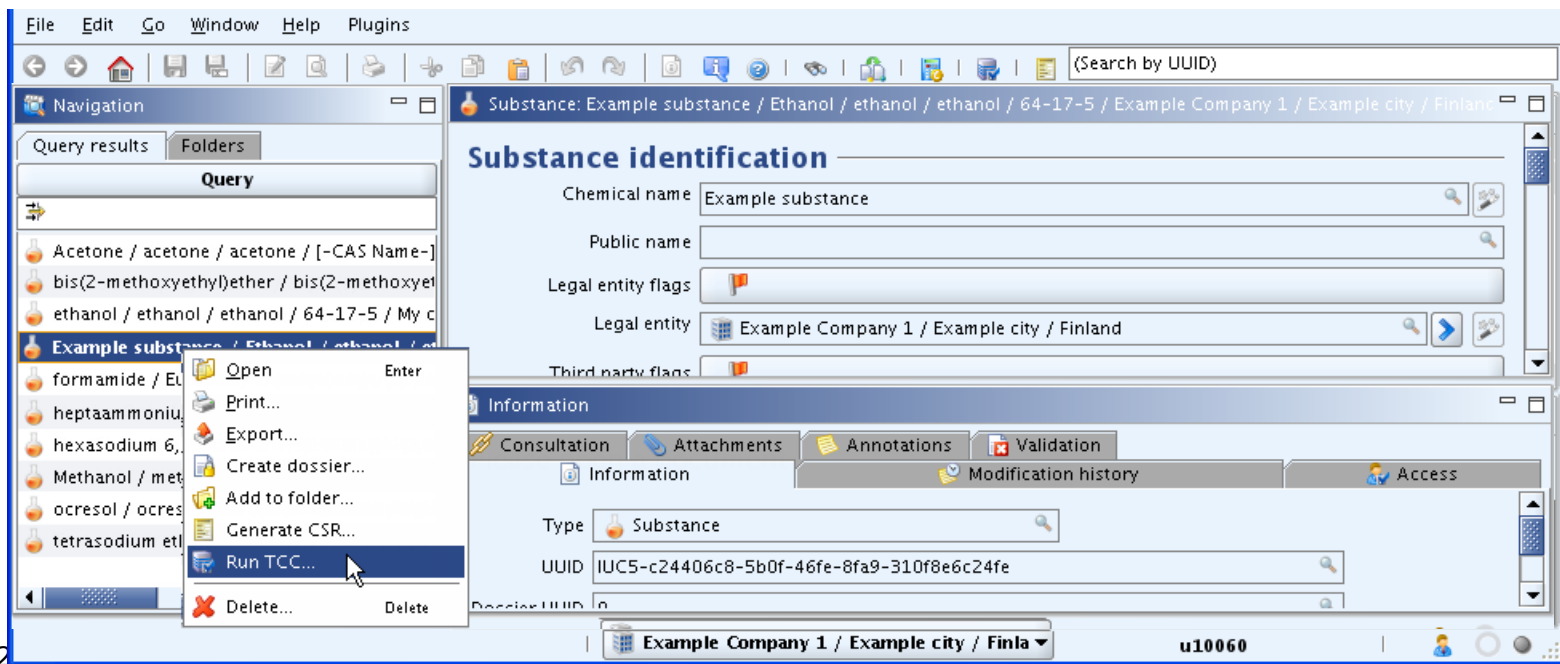
## Before creating the dossier...

- 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



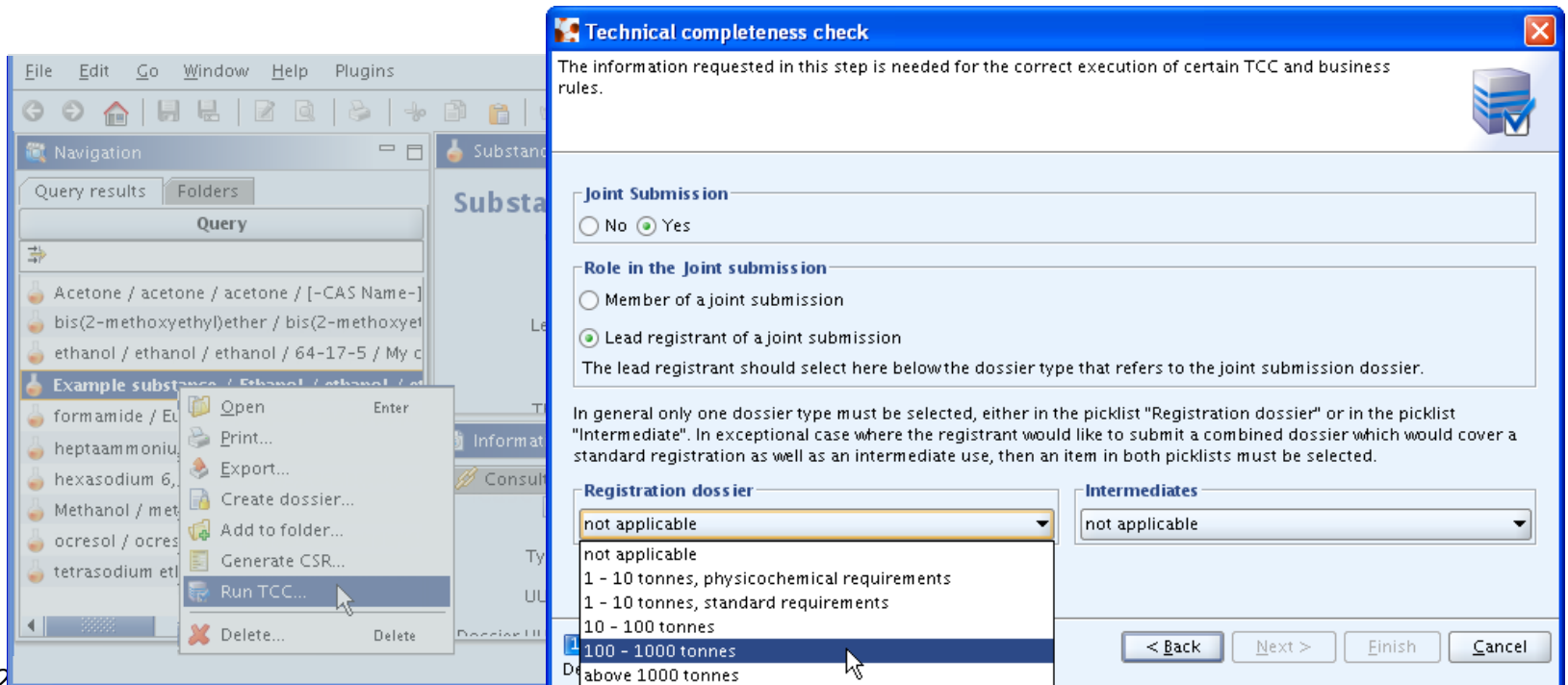
## Before creating the dossier...

- 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



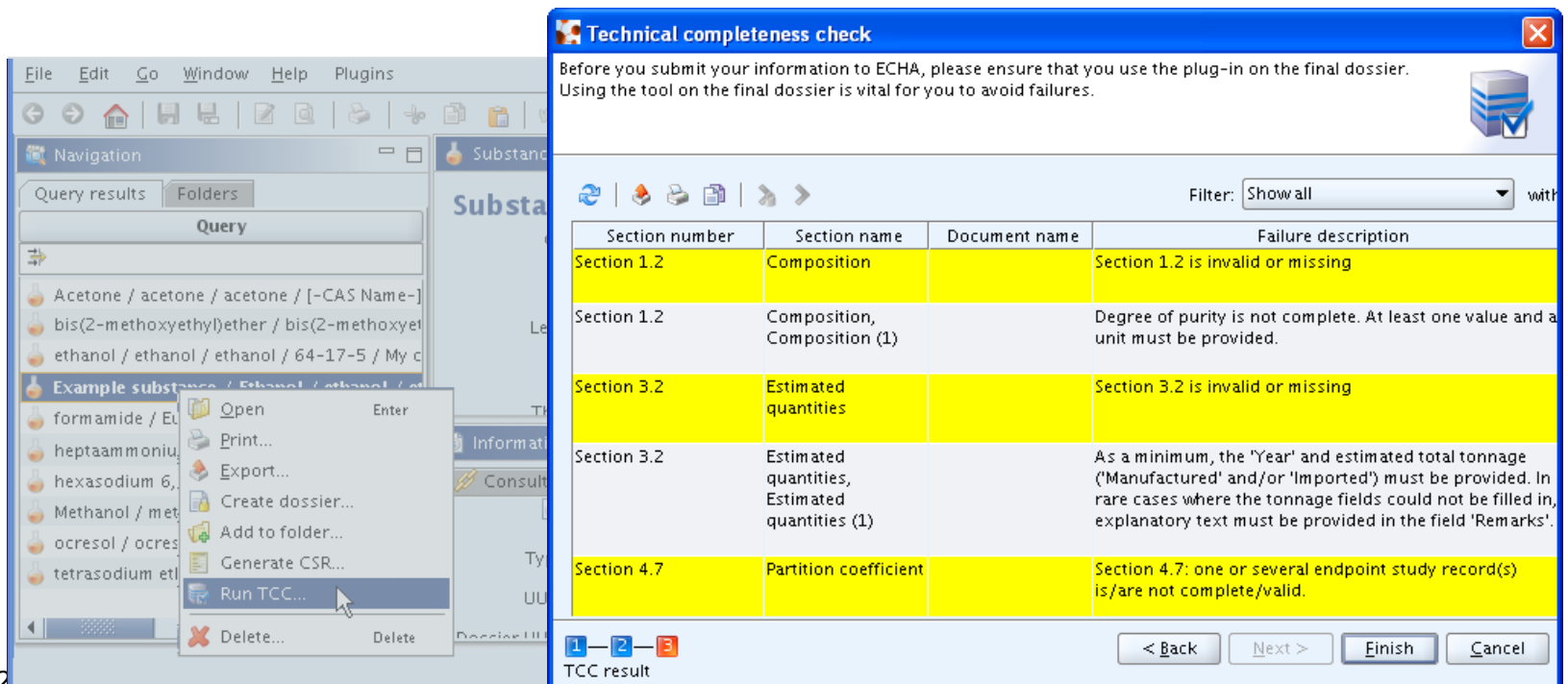
## Before creating the dossier...

- 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



## 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



**Technical completeness check**

Before you submit your information to ECHA, please ensure that you use the plug-in on the final dossier. Using the tool on the final dossier is vital for you to avoid failures.

Filter: Show all with

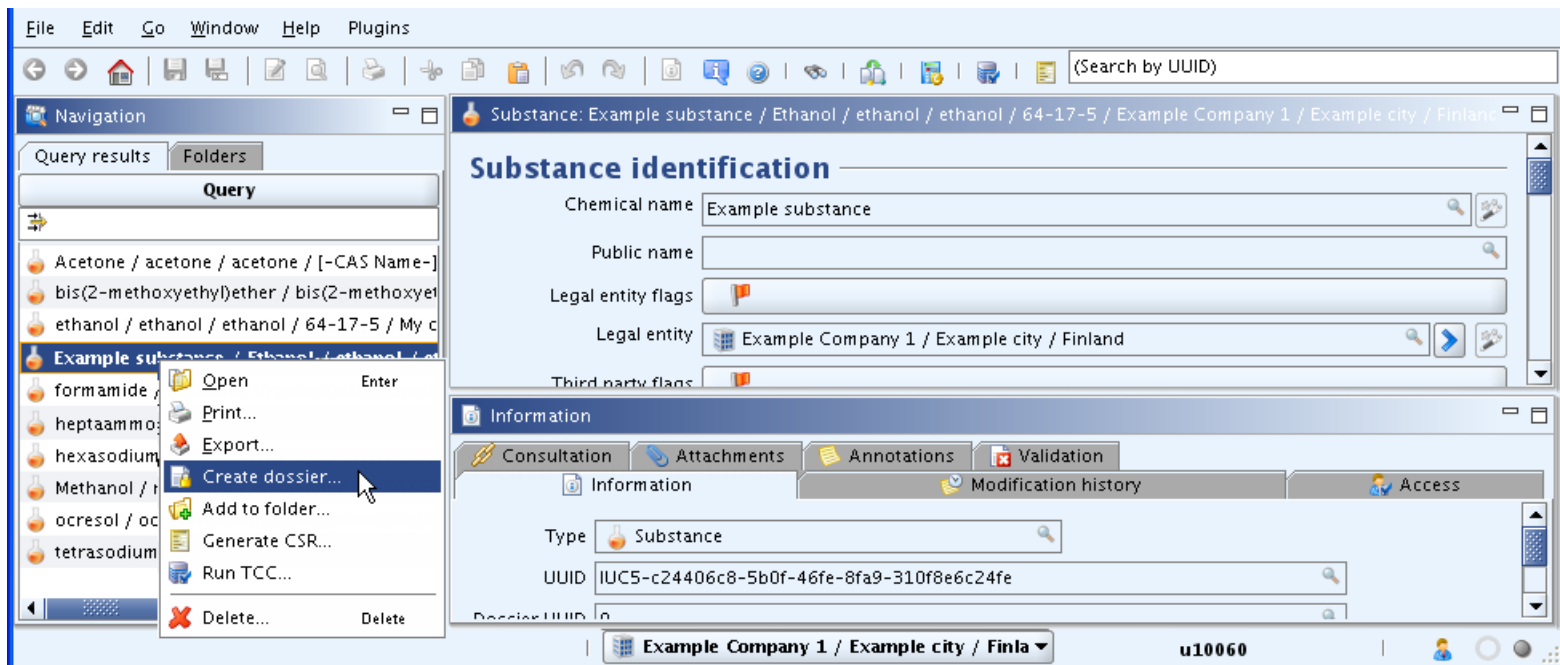
Section number	Section name	Document name	Failure description
Section 1.2	Composition		Section 1.2 is invalid or missing
Section 1.2	Composition, Composition (1)		Degree of purity is not complete. At least one value and a unit must be provided.
Section 3.2	Estimated quantities		Section 3.2 is invalid or missing
Section 3.2	Estimated quantities, Estimated quantities (1)		As a minimum, the 'Year' and estimated total tonnage ('Manufactured' and/or 'Imported') must be provided. In rare cases where the tonnage fields could not be filled in, explanatory text must be provided in the field 'Remarks'.
Section 4.7	Partition coefficient		Section 4.7: one or several endpoint study record(s) is/are not complete/valid.

TCC result

< Back Next > Finish Cancel

## How to create a dossier

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

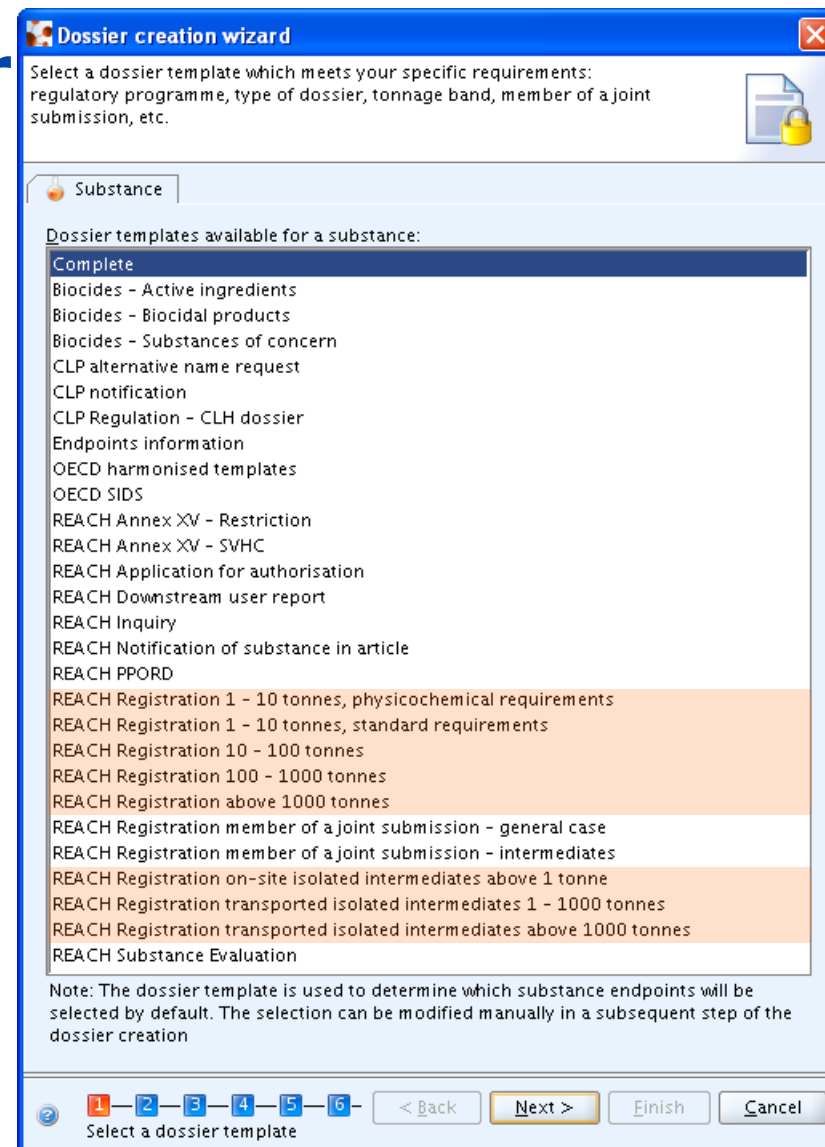




# How to create a dossier

- 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")



**Dossier creation wizard**

Select all Confidentiality and Regulatory purpose flags or clear checkboxes for properties for which the information shall not be included into the dossier  
Dossier template: REACH Registration 100 - 1000 tonnes

**Confidentiality**

Deselect all

- CBI - confidential business information
- IP - intellectual property
- no PA - not public available
- Not confidential

**Use restricted to selected regulatory programmes**

Deselect all

- EU: BPD - Biocidal Products Directive 98/8/EC
- EU: CLP - Classification, Labelling and Packaging
- EU: PPP - Plant Protection Products Directive 91/414/EEC
- EU: REACH - Registration, Evaluation and Authorisation of Chemicals
- CA: CEPA - Existing Substances Program under CEPA
- CA: PCPA - Pest Control Products Act
- JP: CSCL - Chemical Substances Control Law
- OECD: HPVC - HPV Chemicals Programme
- US: EPA HPVC - HPV Chemical Challenge Programme
- US: FIFRA - Federal Insecticide, Fungicide, and Rodenticide Act
- US: TSCA - Toxic Substances Control Act
- Any other
- No regulatory purpose

Note: for a REACH dossier, all information should be part of the dossier, i.e. all flags should be selected or the default values should be used

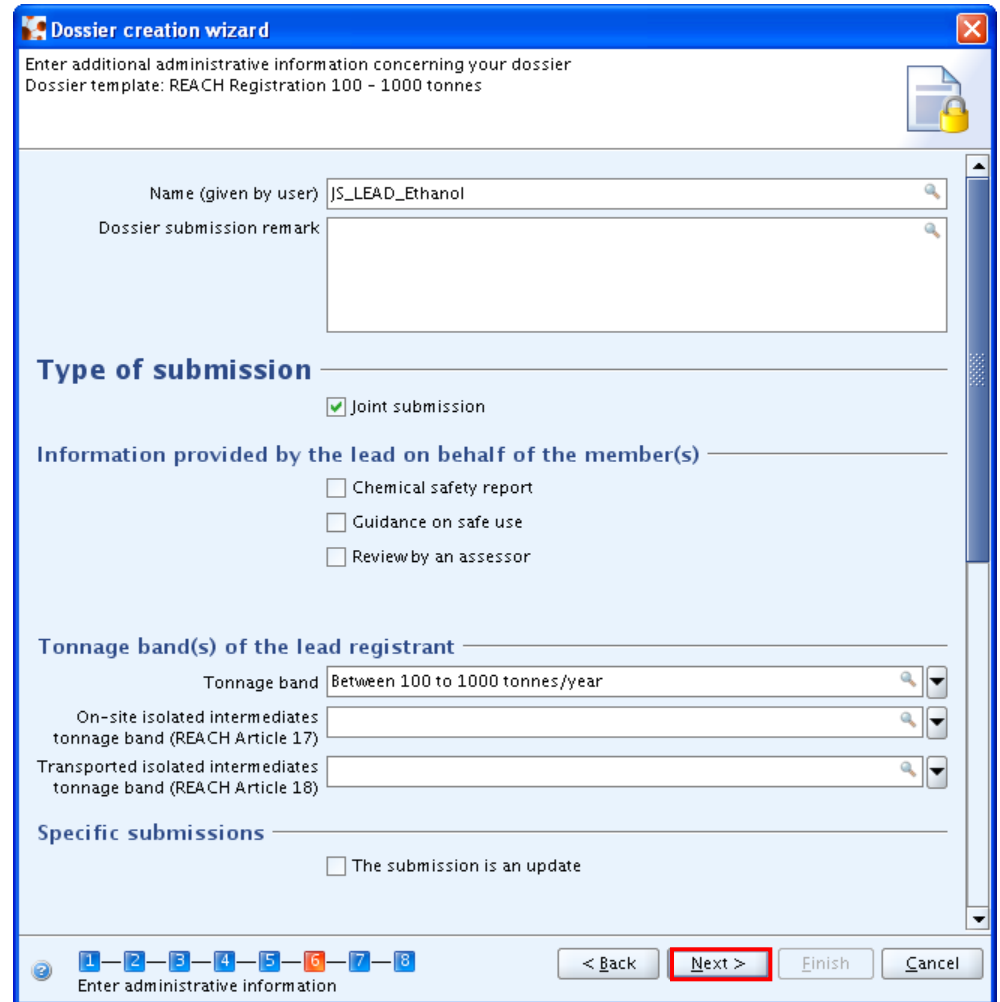
1 2 3 4 5 6 < Back Next > Finish Cancel

Select data protection flags

# How to create a dossier

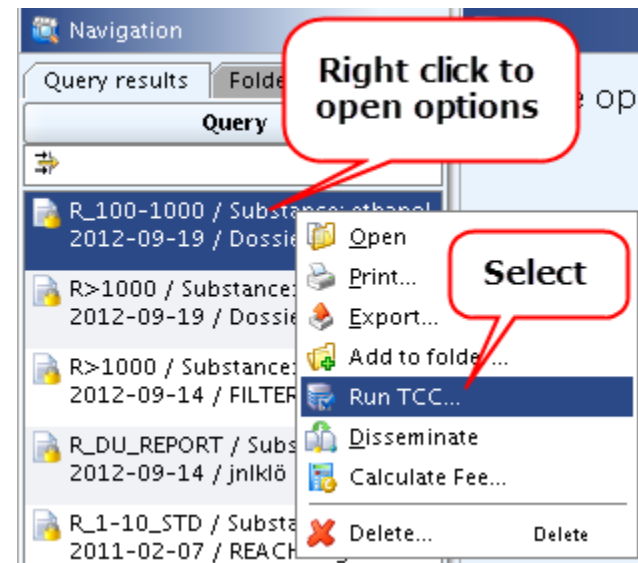
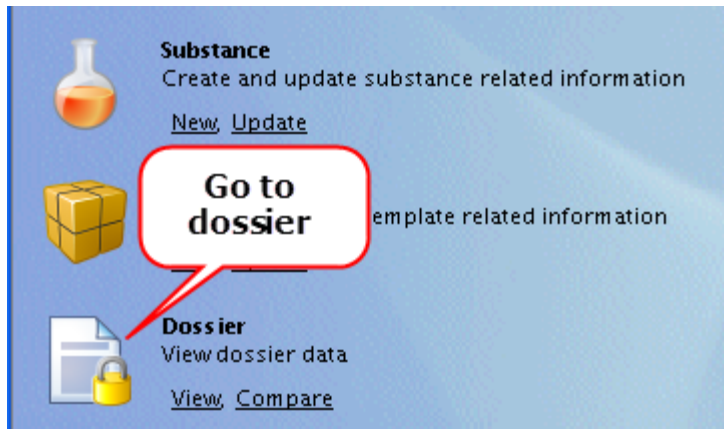
- Fill in dossier header information
- Joint submission
- Indicate here your own tonnage band
- Indicate which information you provide
- Complete dossier creation wizard

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



The screenshot shows the 'Dossier creation wizard' window. The title bar reads 'Dossier creation wizard'. Below the title bar, the text says 'Enter additional administrative information concerning your dossier' and 'Dossier template: REACH Registration 100 - 1000 tonnes'. The main content area contains several sections: 'Name (given by user)' with a text box containing 'JS\_LEAD\_Ethanol'; 'Dossier submission remark' with a large empty text area; 'Type of submission' with a checked checkbox for 'Joint submission'; 'Information provided by the lead on behalf of the member(s)' with three unchecked checkboxes: 'Chemical safety report', 'Guidance on safe use', and 'Review by an assessor'; 'Tonnage band(s) of the lead registrant' with a dropdown menu set to 'Between 100 to 1000 tonnes/year', and two more dropdown menus for 'On-site isolated intermediates tonnage band (REACH Article 17)' and 'Transported isolated intermediates tonnage band (REACH Article 18)'; and 'Specific submissions' with an unchecked checkbox for 'The submission is an update'. At the bottom, there is a progress bar with 8 steps, where step 6 is highlighted in red. To the right of the progress bar are buttons for '< Back', 'Next >', 'Finish', and 'Cancel'. The 'Next >' button is highlighted with a red border.

# 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

**Technical completeness check**

Before you submit your information to ECHA, please ensure that you use the plug-in on the final dossier. Using the tool on the final dossier is vital for you to avoid failures.

Filter: Showall with type failure, warning

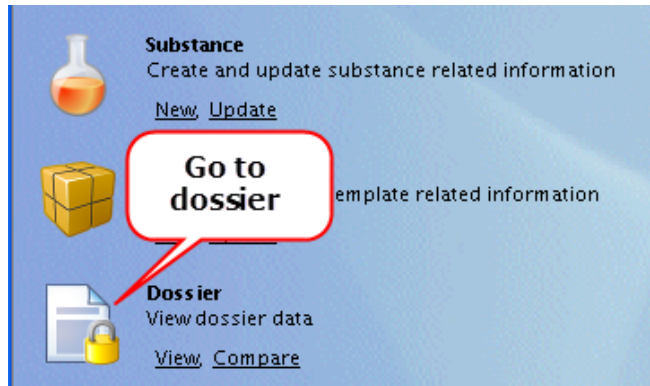
Section number	Section name	Document name	Failure description	Type
Section 13	Assessment Reports		Section 13 is invalid or missing. A CSR or a justification for not providing a CSR must be included. - In order to submit a CSR, one must select 'REACH Chemical safety report (CSR)' in the field 'Type of report' and attach the CSR in the field 'Document'. - In order to submit a justification for not providing a CSR, one must select 'REACH Chemical safety report (CSR)' in the field 'Type of report' and provide the justification for not providing the CSR either in the field 'Remarks' or in the field 'Discussion'. - If you are providing another type of assessment report in addition to a CSR, you must make a selection in 'Type of report' and attach the report in the field 'Document', or include text in the field 'Remarks' or in the field 'Discussion'.	TCC failure
Section 2	Classification and Labelling		Failure in Business Rule BR054	BR failure
Section 2	Classification and Labelling		You have provided the C&L information in an incorrect format. Please respect the deadlines concerning the submission of C&L information according to DSD and GHS format.	BR failure
Section 1.1	Identification		Failure in Business Rule BR090	BR failure
Section 1.1	Identification		The substance is specified as a mono-constituent in section 1.1. The first composition block of section 1.2 is expected to contain a single reference substance that has the same UUID than the reference substance of section 1.1. Note: The UUID of the reference substances is indicated in the 'Information' pane of IUCLID 5.	BR failure

TCC engine version: 6.06 Business rules version: 2.2.8 Completeness rules version: 2.2.7 Substance identity rules version: 1.1.2

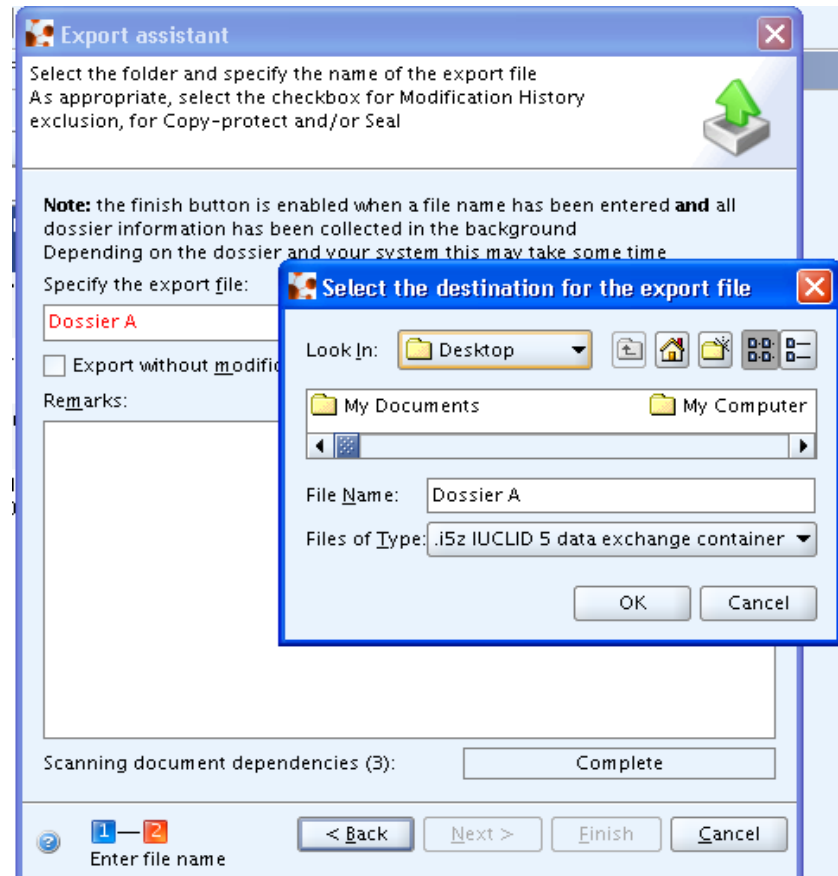
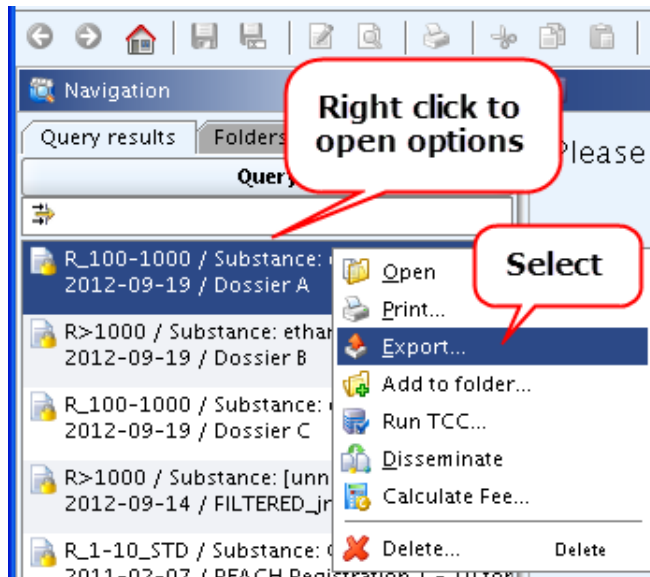
TCC result

< Back Next > Finish Cancel

# Export the dossier



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



**Thank you**

