

Familiarising yourself with IUCLID 5

*IUCLID 5 Basics training by ECHA
27 September 2011*

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Training objectives

- This presentation is targeted to the HelpNet-4 *hands-on training* participants.
- By the end of this presentation the participants will know how to work with IUCLID 5 interface, edit data in the substance datasets, create dossiers and use the Technical completeness check (TCC) plug-in.



Outline

- IUCLID 5 User interface
- A Dossier anatomy
- Reference substance
- Substance dataset
 - Basic functionalities on substance datasets
- Dossier
 - Basic functionalities on dossiers
- Technical completeness check (TCC) plug-in
 - Basic functionalities on substance datasets
 - Basic functionalities on dossiers



IUCLID 5 User interface





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
Create and update mixture related information
[New](#) [Update](#)

Category
Create and update category related information
[New](#) [Update](#)

Tasks: Daily work

Inventories

Inventory
View EC inventory related information
[View](#)

Reference substance
Create and update reference substance related information
[New](#) [Update](#)

Literature reference
View and exchange literature reference inventory related information
[View](#) [Exchange](#)

Inventories: Substance ID & Literature references

Tools and administration

Manage users, roles, preferences, etc.
[User preferences](#) [Set password](#) [User management](#) [Role management](#)

Bulk export
Export multiple documents

Import
Import data from other IUCLID systems
[Import](#)

Tools & Administration

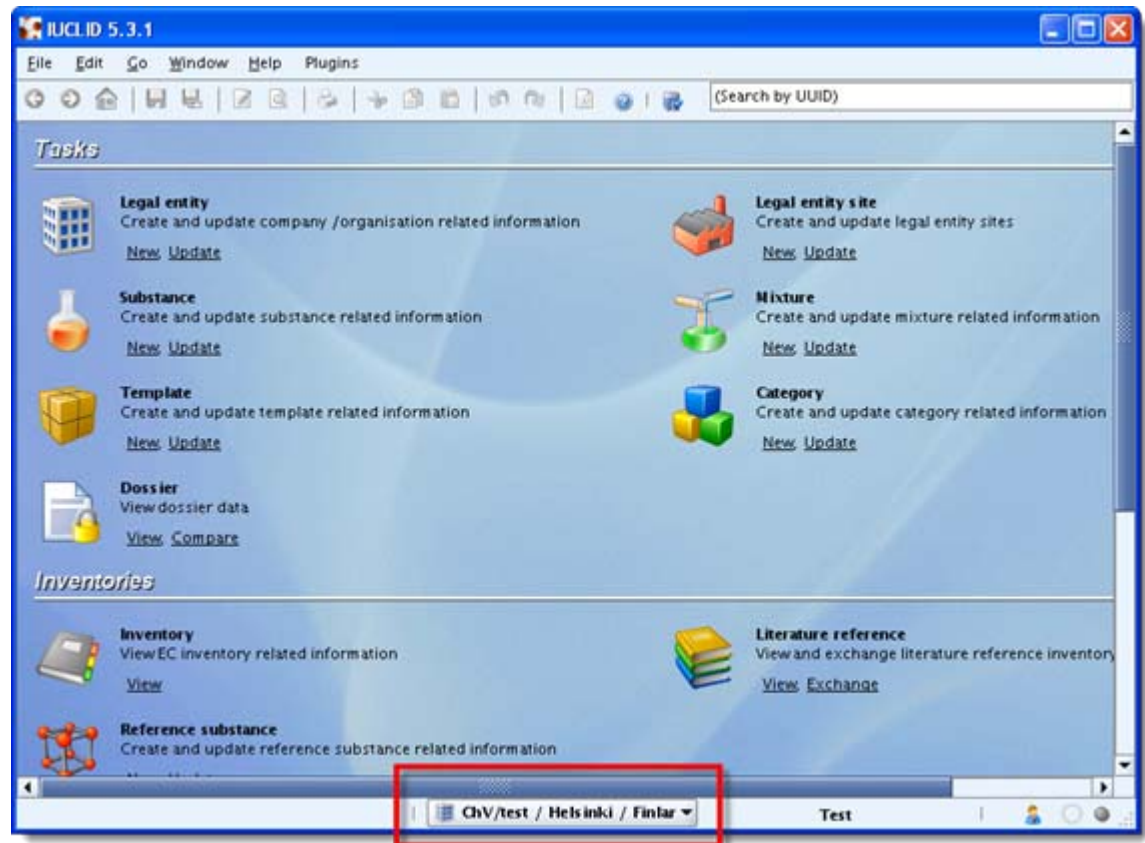
Basic functionalities on the IUCLID 5 user interface



Before you start !

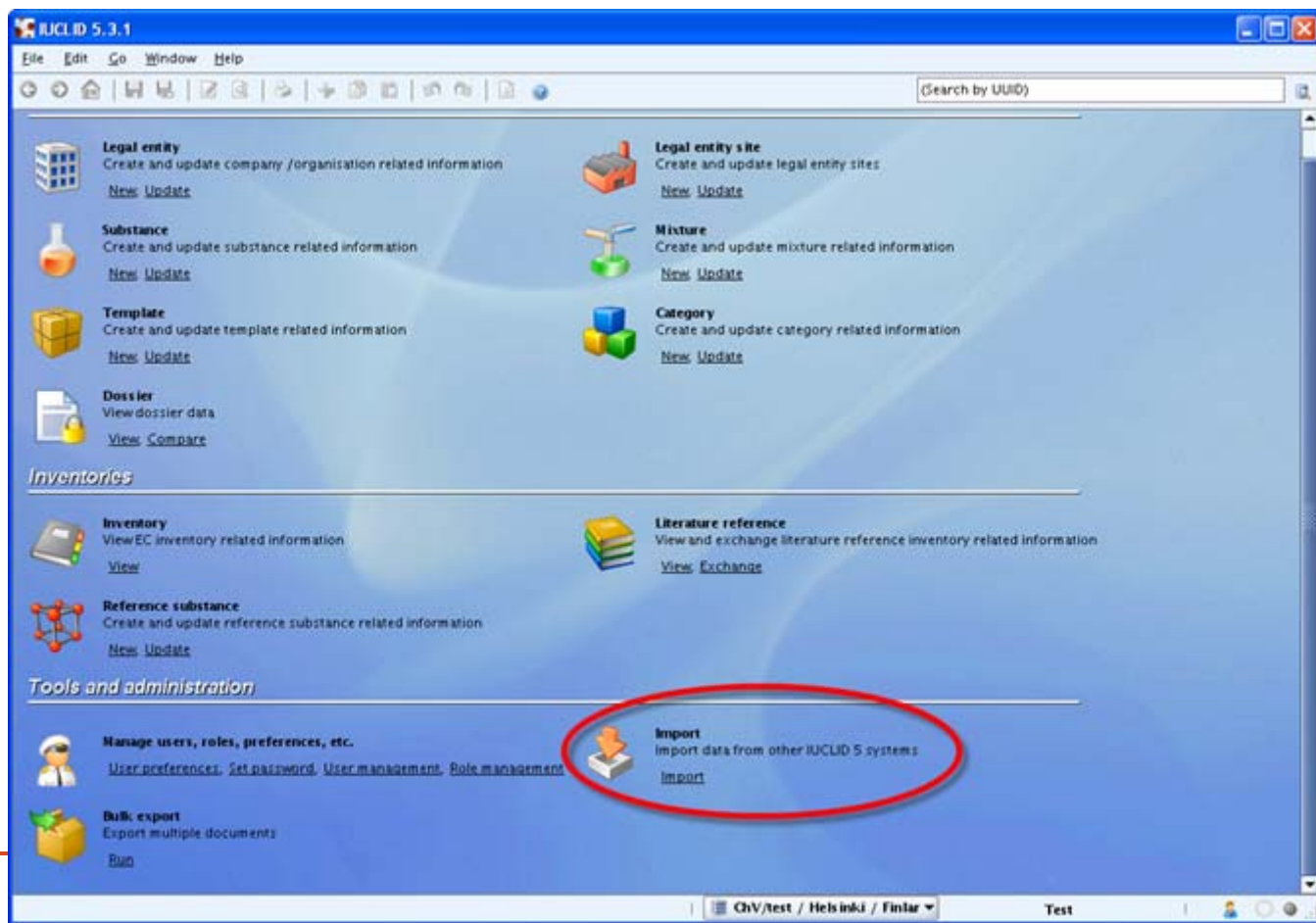


Ensure that the **IUCLID Legal Entity** corresponds to the your Legal entity in REACH-IT



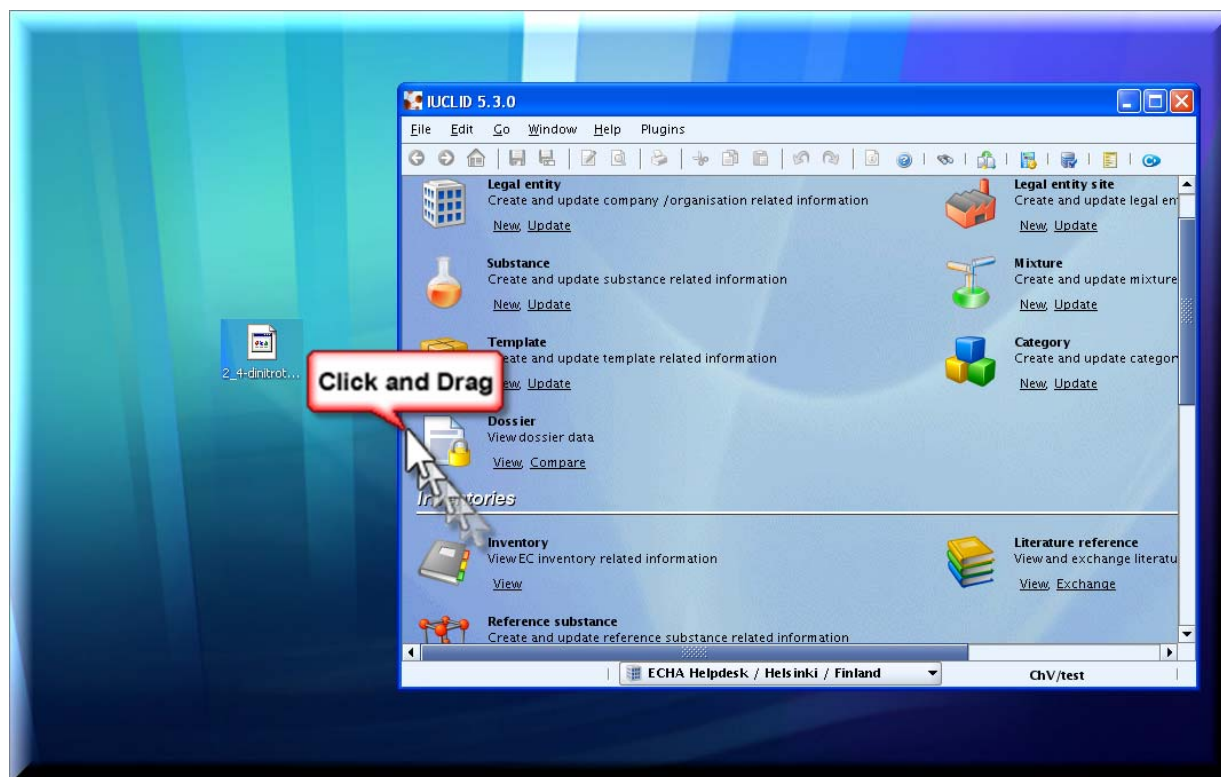
How to import a file into IUCLID 5

‘Import’
functionality

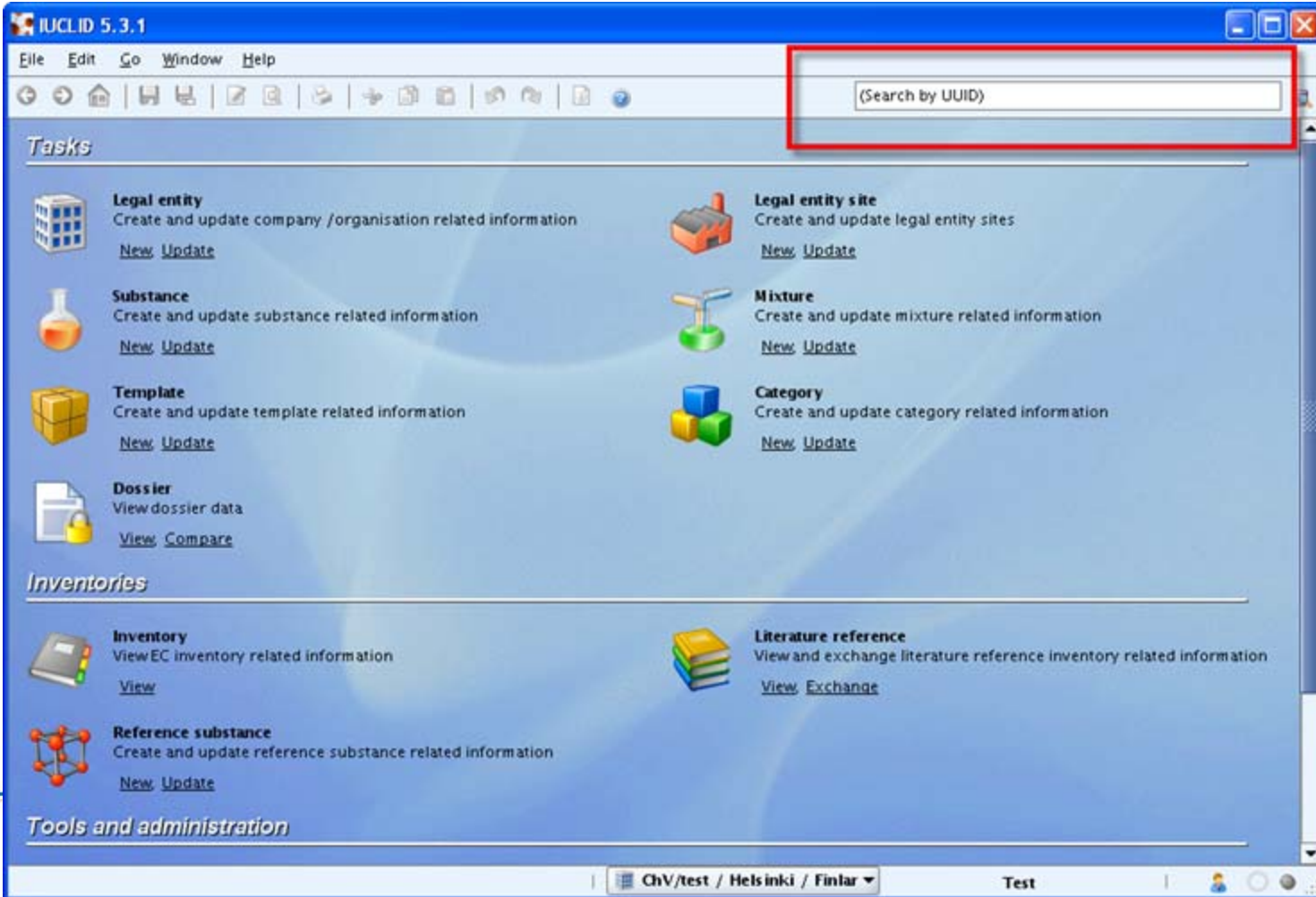


How to import a file into IUCLID 5

Click and Drag
the file into
the home panel



How to search for a file with the UUID



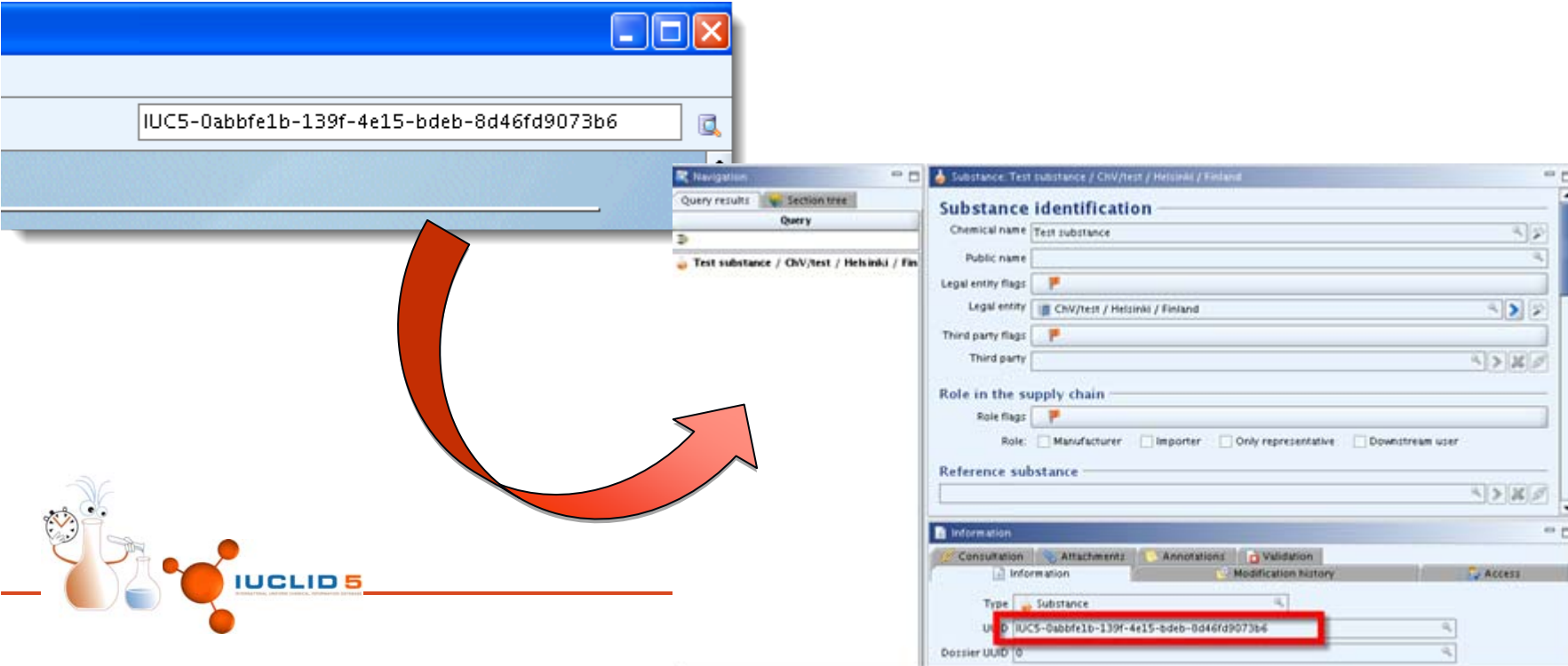
The screenshot shows the IUCLID 5.3.1 software interface. At the top, there is a menu bar with 'File', 'Edit', 'Go', 'Window', and 'Help'. Below the menu bar is a toolbar with various icons. A search bar is located in the top right corner, containing the text '(Search by UUID)'. The main area is divided into sections: 'Tasks' and 'Inventories'. Under 'Tasks', there are icons and descriptions for 'Legal entity', 'Substance', 'Template', 'Dossier', 'Legal entity site', 'Mixture', and 'Category'. Under 'Inventories', there are icons and descriptions for 'Inventory', 'Reference substance', and 'Literature reference'. At the bottom, there is a status bar with the text 'ChV/test / Helsinki / Finlar' and 'Test'.



Example- How to search for a file with the UUID

Looking for a substance dataset with UUID

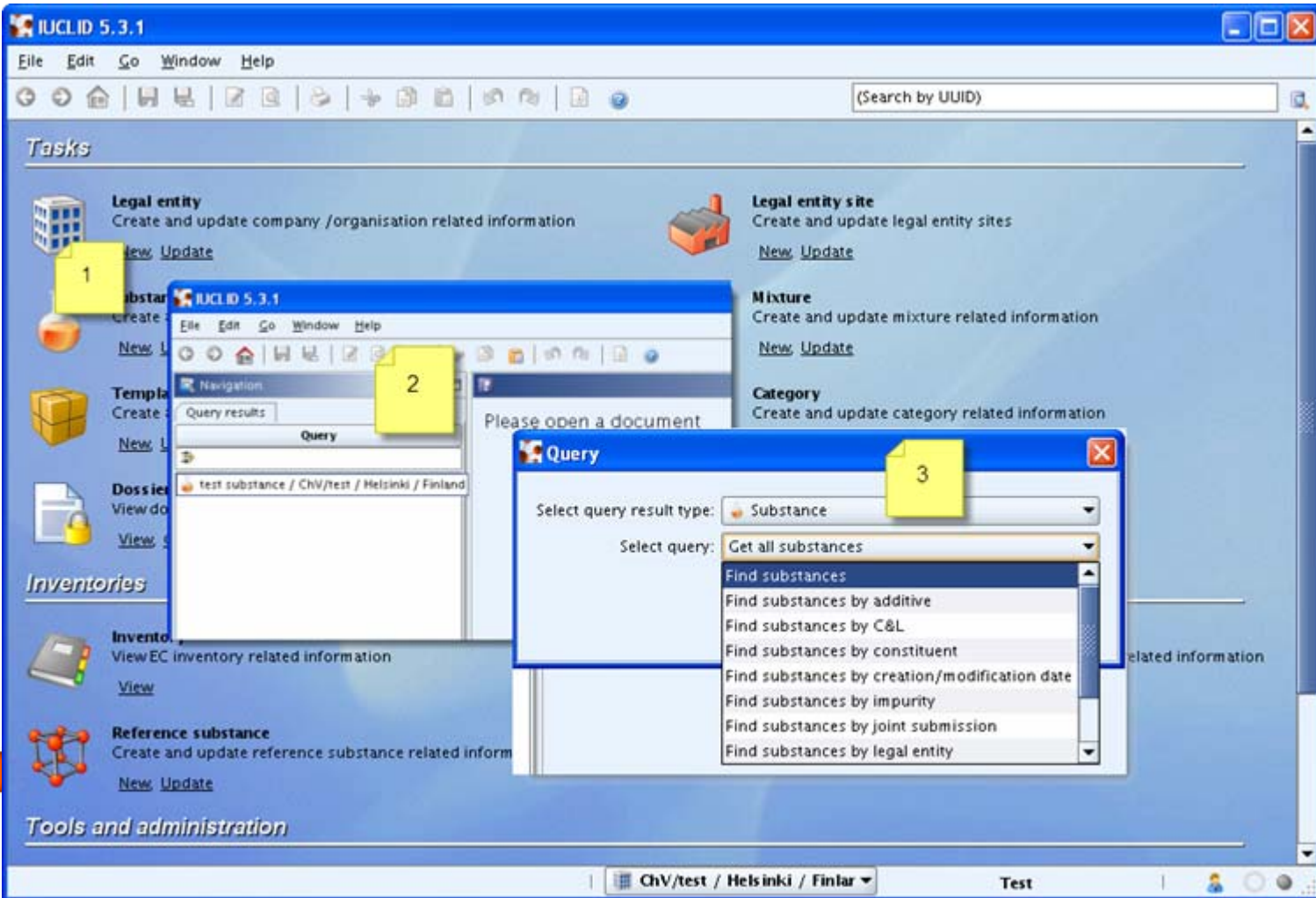
IUC5-0abbfe1b-139f-4e15-bdeb-8d46fd9073b6



The image shows a screenshot of the ECHA IUCLID 5 web interface. At the top, a search bar contains the UUID: IUC5-0abbfe1b-139f-4e15-bdeb-8d46fd9073b6. Below the search bar, a navigation pane shows a tree structure with the selected path: Test substance / CHV/test / Helsinki / Fin. The main content area displays the 'Substance identification' details for 'Test substance', including fields for Chemical name, Public name, Legal entity flags, Legal entity (CHV/test / Helsinki / Finland), Third party flags, and Role in the supply chain. The 'Information' section at the bottom shows the 'Type' as 'Substance' and the 'UID' as 'IUC5-0abbfe1b-139f-4e15-bdeb-8d46fd9073b6', which is highlighted with a red box. A large red arrow points from the search bar to the UID field in the substance details.



How to search for a substance dataset



The screenshot displays the IUCLID 5.3.1 software interface. The main window has a menu bar (File, Edit, Go, Window, Help) and a toolbar. A search bar at the top right is labeled "(Search by UUID)". The interface is divided into several sections: "Tasks" (Legal entity, Legal entity site, Mixture, Category), "Inventories" (Inventory, Reference substance), and "Tools and administration". A "Query" dialog box is open, showing "Select query result type:" set to "Substance" and "Select query:" with a dropdown menu listing various search criteria. Three yellow sticky notes are placed on the interface: "1" is on the "Legal entity" task icon, "2" is on the "Query" dialog box, and "3" is on the "Substance" dropdown menu. A small cartoon character is visible in the bottom left corner.

Tasks

- Legal entity**
Create and update company /organisation related information
[New](#) [Update](#)
- Legal entity site**
Create and update legal entity sites
[New](#) [Update](#)
- Mixture**
Create and update mixture related information
[New](#) [Update](#)
- Category**
Create and update category related information

Inventories

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

Tools and administration

Query

Select query result type: Substance

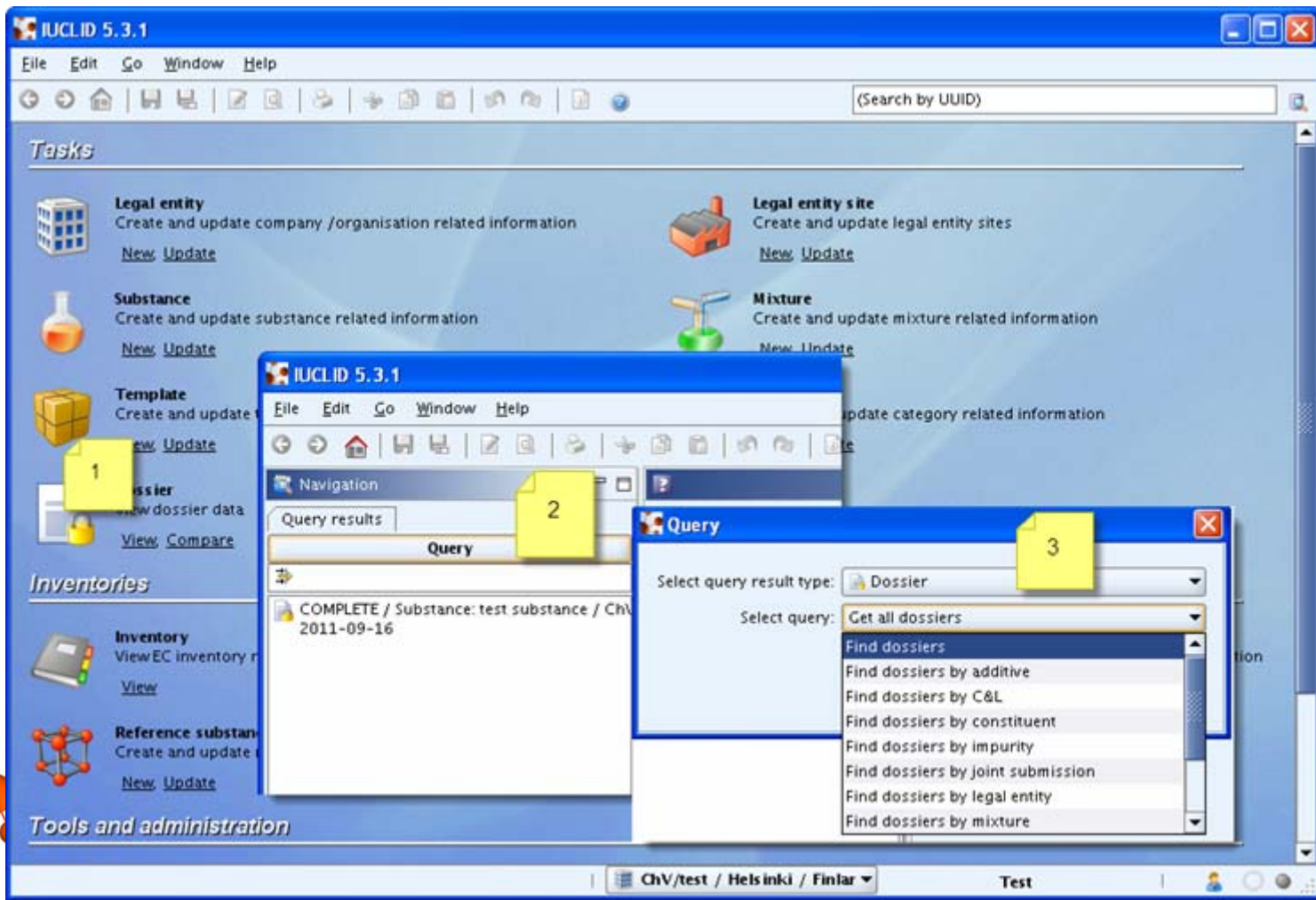
Select query:

- Get all substances
- Find substances
- Find substances by additive
- Find substances by C&L
- Find substances by constituent
- Find substances by creation/modification date
- Find substances by impurity
- Find substances by joint submission
- Find substances by legal entity

ChV/test / Helsinki / Finland

Test

How to search for a dossier



The screenshot displays the IUCLID 5.3.1 software interface. The main window shows a sidebar with navigation options: **Tasks** (Legal entity, Substance, Template, Dossier, Inventory, Reference substance) and **Inventories**. A search bar at the top right is labeled "(Search by UUID)".

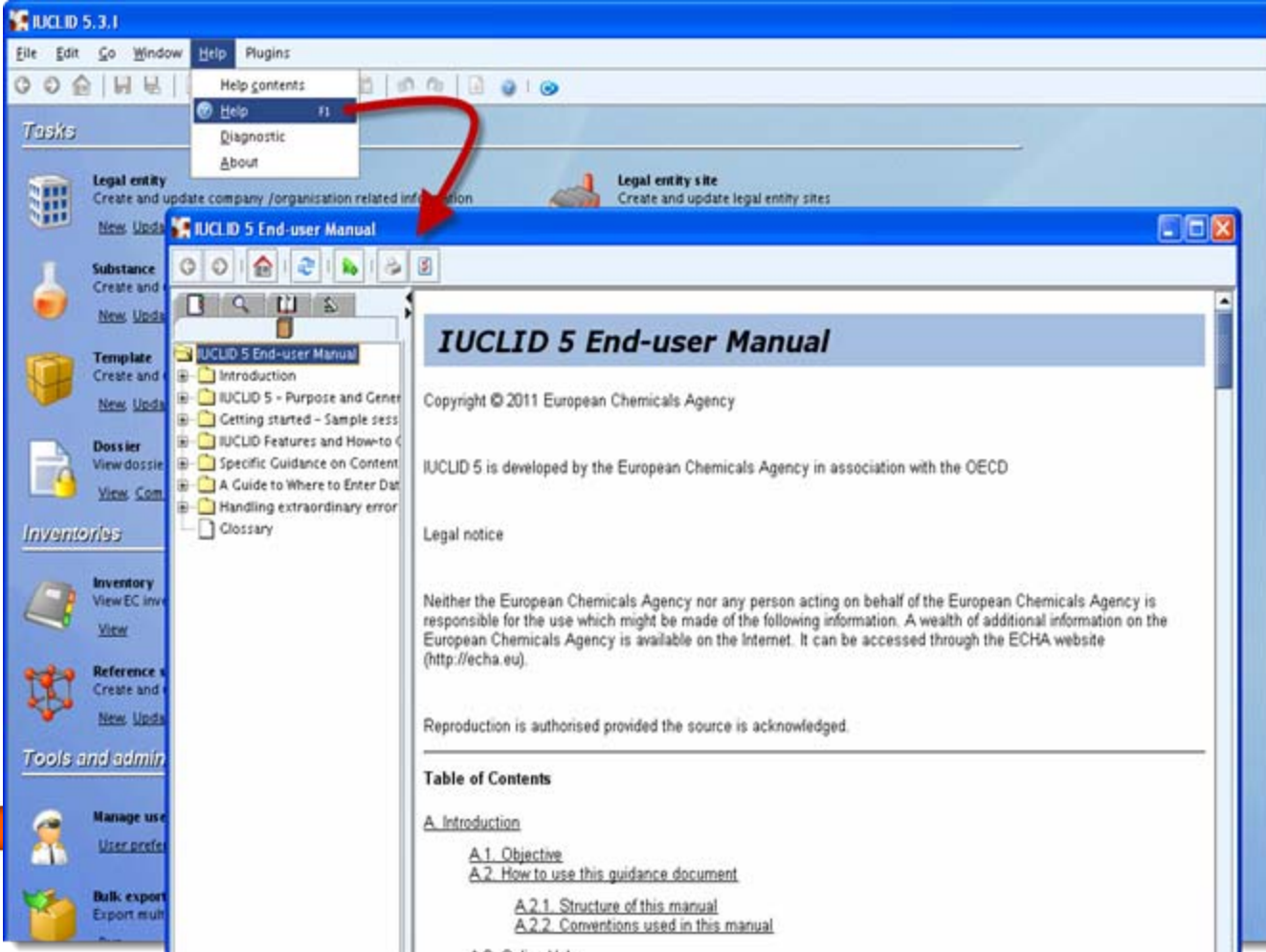
Three yellow sticky notes indicate the search process:

- 1**: Points to the "Dossier" option in the sidebar.
- 2**: Points to the "Query" window, which shows a "Query results" table with one entry: "COMPLETE / Substance: test substance / ChV / 2011-09-16".
- 3**: Points to the "Query" dialog box, which has "Dossier" selected in the "Select query result type:" dropdown and "Find dossiers" selected in the "Select query:" dropdown.

The bottom status bar shows the user is logged in as "ChV/test / Helsinki / Finlar" and is in "Test" mode.



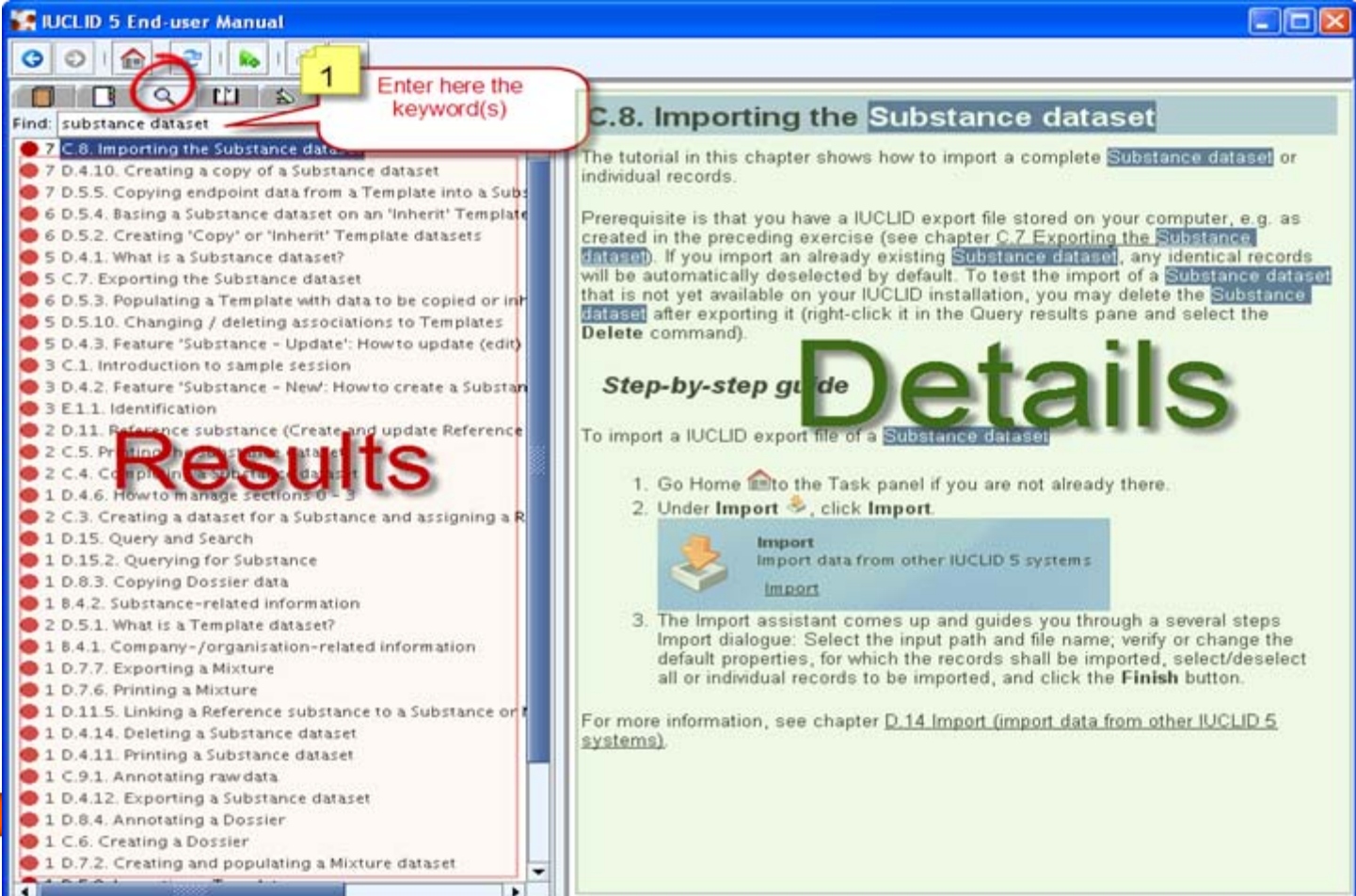
Help functionality



The screenshot displays the IUCLID 5.3.1 software interface. The main window is titled "IUCLID 5.3.1" and features a menu bar with "File", "Edit", "Go", "Window", "Help", and "Plugins". The "Help" menu is open, showing options: "Help contents", "Help" (with a keyboard shortcut "F1" and a red arrow pointing to it), "Diagnostic", and "About". Below the menu bar, there are task panes for "Legal entity", "Substance", "Template", "Dossier", "Inventories", and "Tools and admin". A secondary window titled "IUCLID 5 End-user Manual" is open, displaying the manual's content. The manual includes a table of contents with sections: "A Introduction", "A.1 Objective", "A.2 How to use this guidance document", "A.2.1 Structure of this manual", "A.2.2 Conventions used in this manual", and "A.3 Online Help".



Example: search by keyword



The screenshot shows the IUCLID 5 End-user Manual interface. A search bar at the top left contains the text "substance dataset". A red circle highlights the search icon, and a callout box with the number "1" points to it, containing the text "Enter here the keyword(s)". The left sidebar displays a list of search results, with "C.8. Importing the Substance dataset" highlighted in blue. The main content area shows the text of chapter C.8, including a "Step-by-step guide" and a "Details" section. A large red "Results" watermark is overlaid on the left side of the manual window.

1 Enter here the keyword(s)

Find: substance dataset

Results

C.8. Importing the Substance dataset



The tutorial in this chapter shows how to import a complete **Substance dataset** or individual records.

Prerequisite is that you have a IUCLID export file stored on your computer, e.g. as created in the preceding exercise (see chapter **C.7. Exporting the Substance dataset**). If you import an already existing **Substance dataset**, any identical records will be automatically deselected by default. To test the import of a **Substance dataset** that is not yet available on your IUCLID installation, you may delete the **Substance dataset** after exporting it (right-click it in the Query results pane and select the **Delete** command).

Step-by-step guide

Details

To import a IUCLID export file of a **Substance dataset**

1. Go Home  to the Task panel if you are not already there.
2. Under **Import** , click **Import**.

Import
Import data from other IUCLID 5 systems

[Import](#)

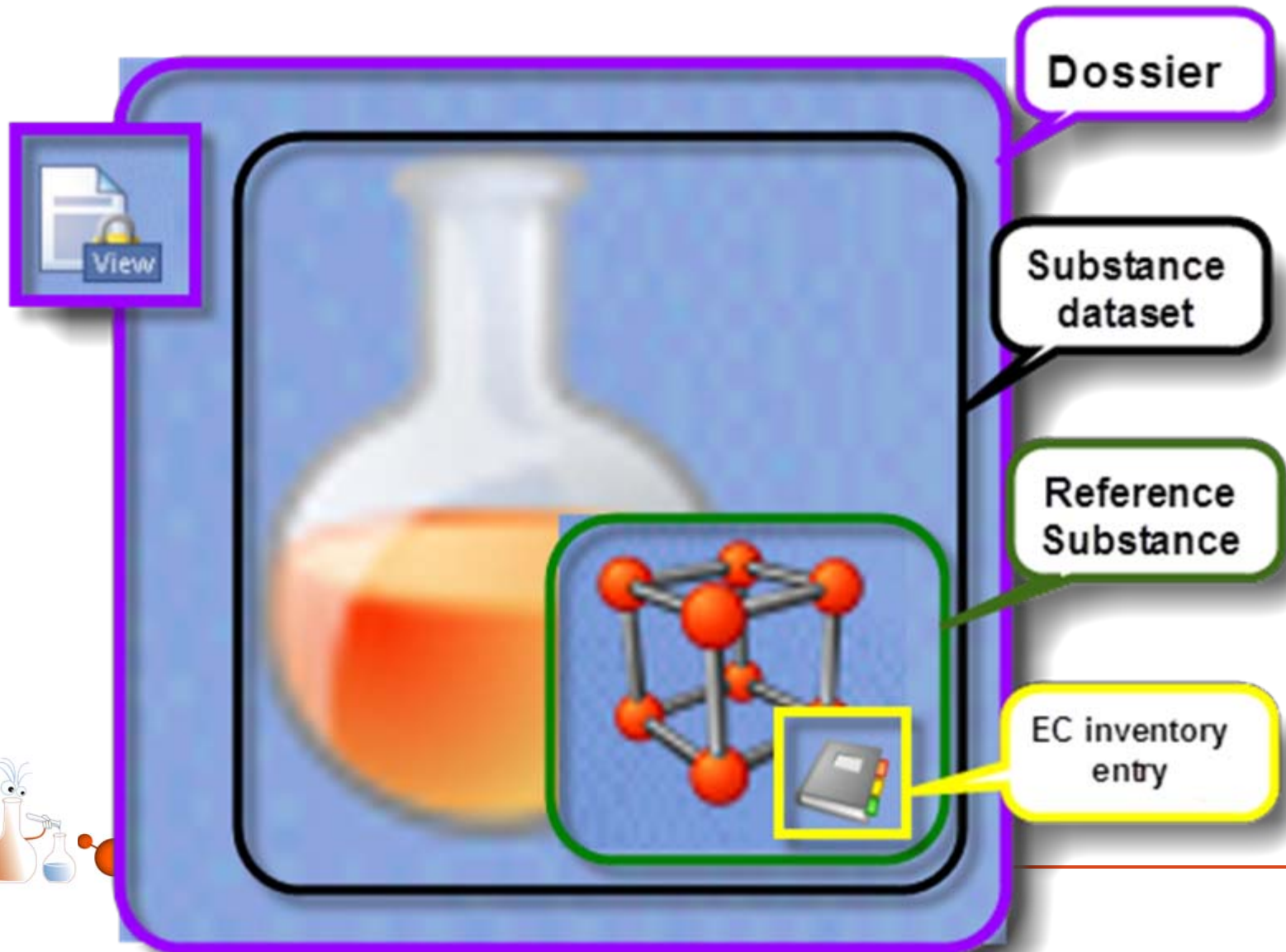
3. The Import assistant comes up and guides you through a several steps Import dialogue: Select the input path and file name; verify or change the default properties, for which the records shall be imported, select/deselect all or individual records to be imported, and click the **Finish** button.

For more information, see chapter **D.14 Import (import data from other IUCLID 5 systems)**.



A Dossier anatomy





Dossier anatomy

- A **dossier** is a ‘snapshot’ of a substance dataset. This means it is on read-only mode (i.e. cannot be modified)
- The **substance dataset** contains all the information of the chemical substance. It is editable
- A **Reference substance** is used in the substance dataset for each constituent, additive, impurity
- The **EC inventory entry** is an integral part of the Reference substance



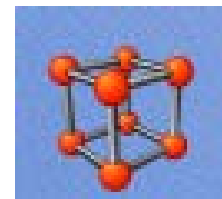
Reference substance



Reference substances inventory

What is it?

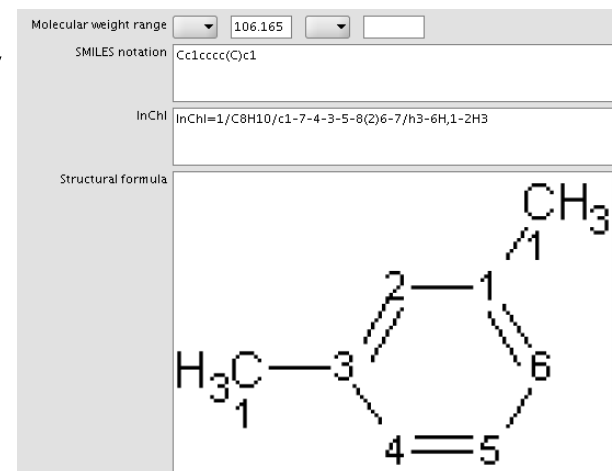
- The **Reference substance inventory** is a local inventory managed and upgraded by the users on their IUCLID installations
- A **Reference substance** is a 'label' to be attached to each of your substances in IUCLID



Reference substances inventory

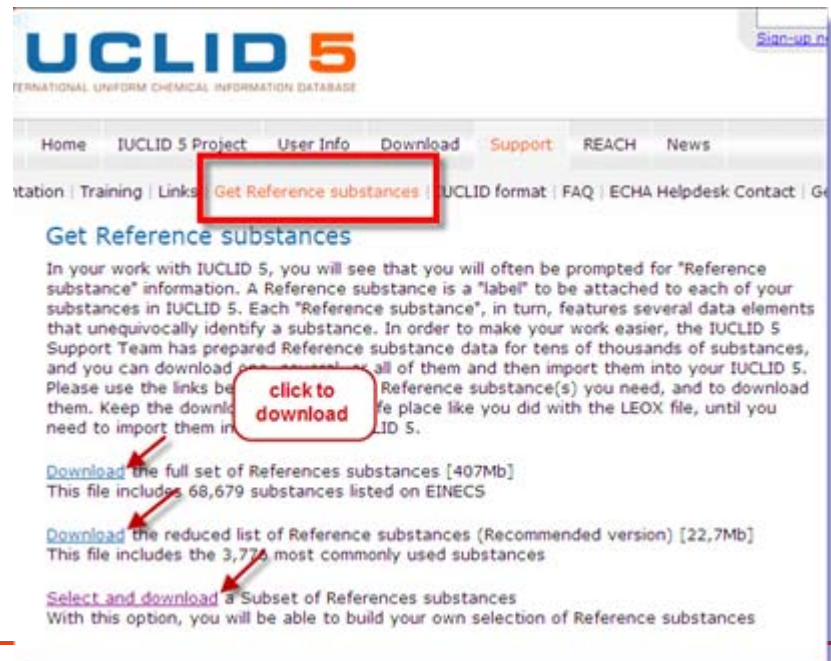
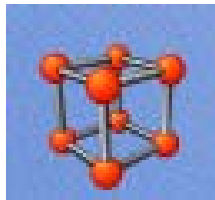
Information contained

- Information on the Substance Identity i.e. IUPAC name and molecular and structural information (including SMILES notation, InCHI..)
- Name(s), EINECS, ELINCS, CAS, Composition... [Identity of the substance Art 10 (a) (ii) – Annex VI, section 2]
- Direct link to EC inventory (*if possible*)



Reference substances inventory

The **Reference substance inventory** is a local inventory managed and upgraded by the users on their IUCLID installations



IUCLID 5
INTERNATIONAL UNIFORM CHEMICAL INFORMATION DATABASE

Home | IUCLID 5 Project | User Info | Download | **Support** | REACH | News

Installation | Training | Links | **Get Reference substances** | IUCLID format | FAQ | ECHA Helpdesk Contact | Get

Get Reference substances

In your work with IUCLID 5, you will see that you will often be prompted for "Reference substance" information. A Reference substance is a "label" to be attached to each of your substances in IUCLID 5. Each "Reference substance", in turn, features several data elements that unequivocally identify a substance. In order to make your work easier, the IUCLID 5 Support Team has prepared Reference substance data for tens of thousands of substances, and you can download a file containing all of them and then import them into your IUCLID 5. Please use the links below to download the Reference substance(s) you need, and to download them. Keep the downloaded file in the same place like you did with the LEOX file, until you need to import them into IUCLID 5.

click to download

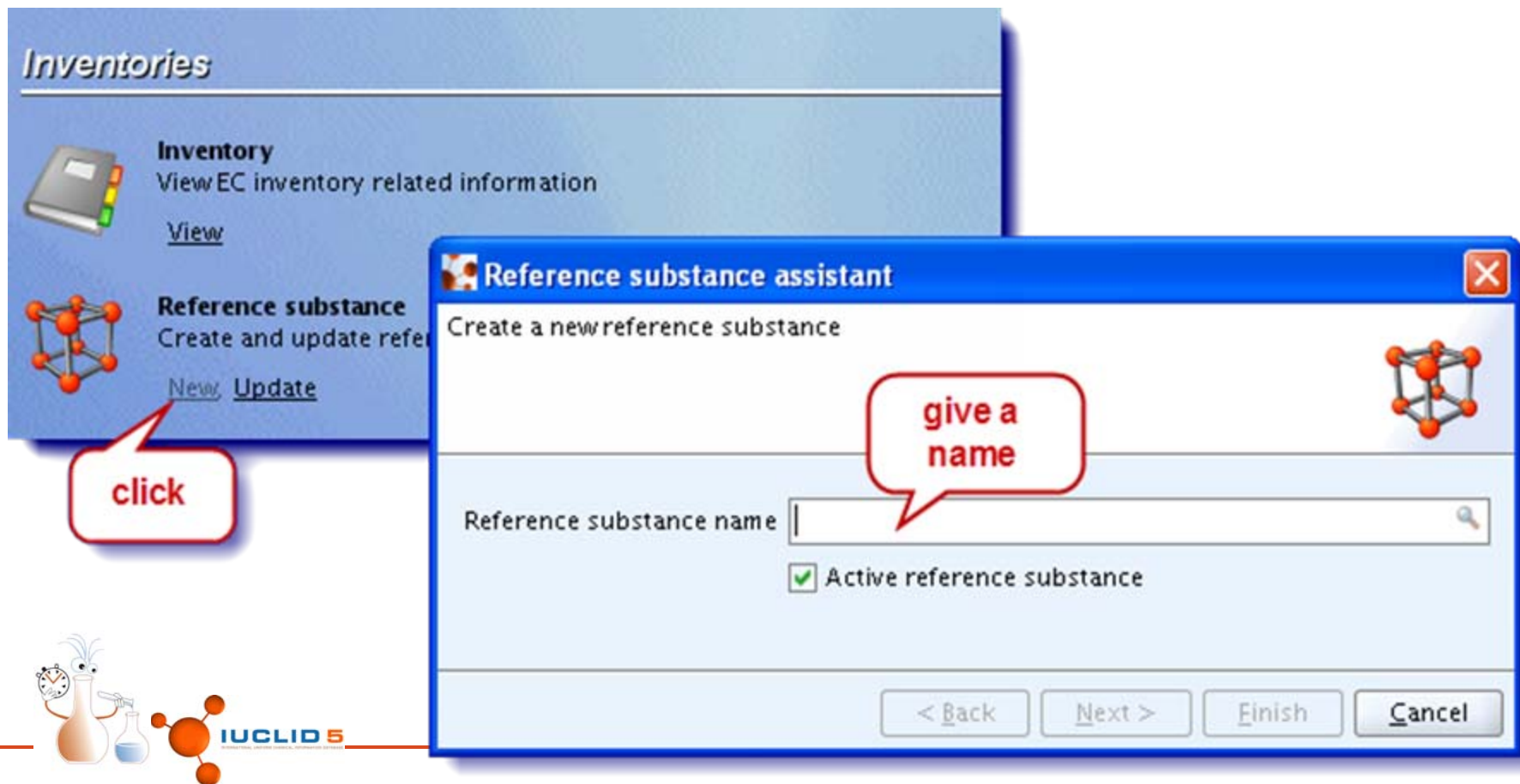
[Download](#) the full set of References substances [407Mb]
This file includes 66,679 substances listed on EINECS

[Download](#) the reduced list of Reference substances (Recommended version) [22,7Mb]
This file includes the 3,774 most commonly used substances

[Select and download](#) a Subset of References substances
With this option, you will be able to build your own selection of Reference substances



How do I create my own Reference substance?



Inventories

Inventory
View EC inventory related information
[View](#)

Reference substance
Create and update reference substances
[New](#) [Update](#)

click

Reference substance assistant


Create a new reference substance

give a name

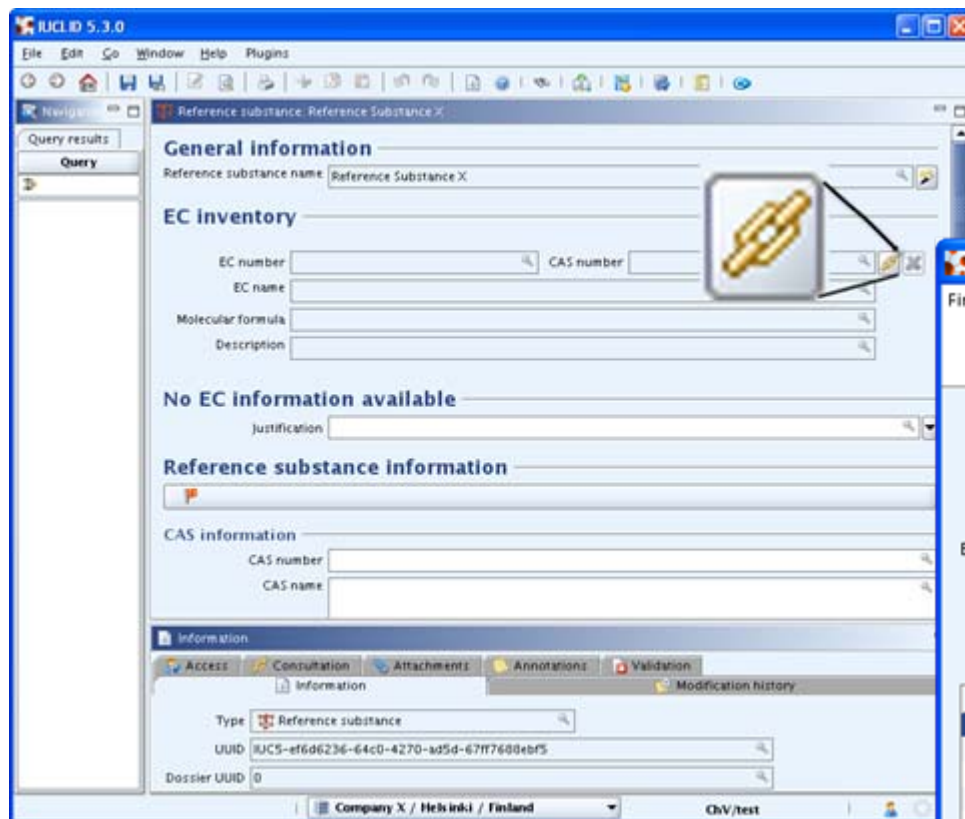
Reference substance name

Active reference substance

< Back Next > Finish Cancel

 IUCLID 5

How do I create my own Reference substance?



IUCLID 5.3.0

File Edit Go Window Help Plugins

Reference substance: Reference Substance X

General information

Reference substance name: Reference Substance X

EC inventory

EC number: CAS number:

EC name:

Molecular formula:

Description:

No EC information available

Justification:

Reference substance information

CAS information

CAS number:

CAS name:

Information

Access Consultation Attachments Annotations Validation

Information

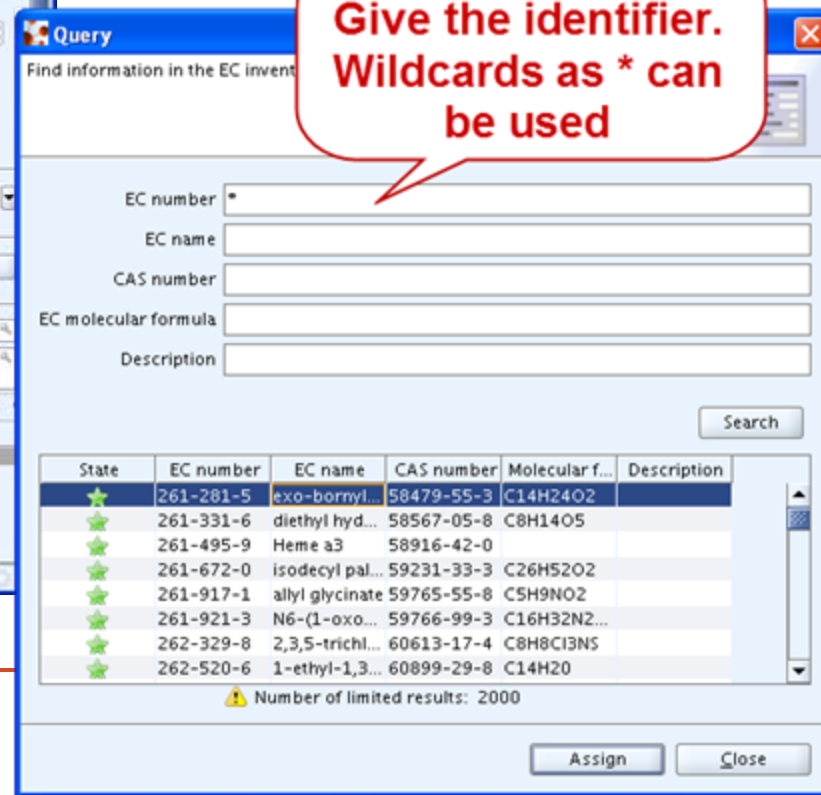
Type: Reference substance

UUID: IUCL5-ef6d6236-64c0-4270-a95d-67ff7680ebf5

Dossier UUID: 0

Company X / Helsinki / Finland

ChV/test



Query

Find information in the EC inventory

Give the identifier. Wildcards as * can be used

EC number: *

EC name:

CAS number:

EC molecular formula:

Description:

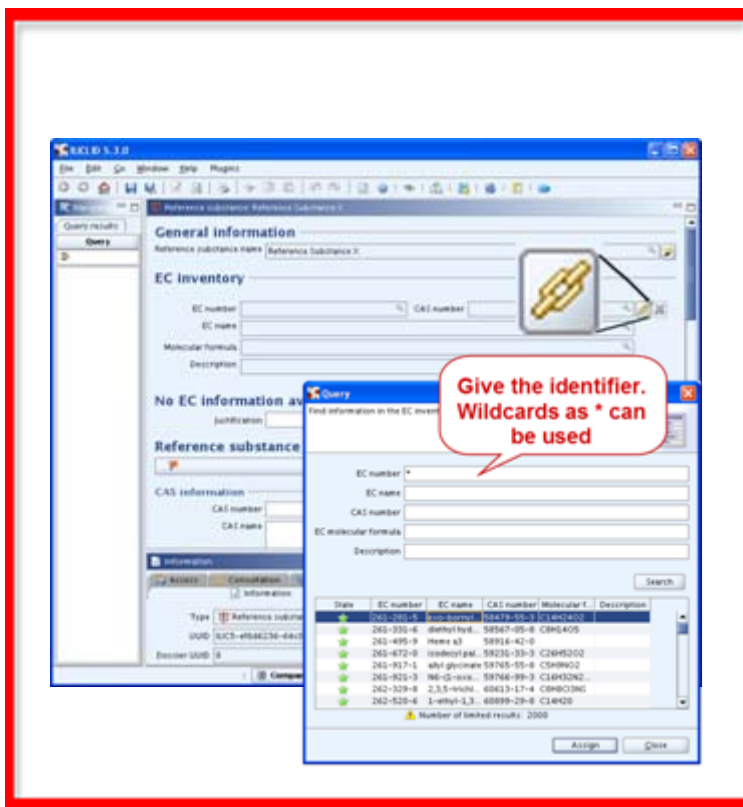
Search

State	EC number	EC name	CAS number	Molecular f...	Description
★	261-281-5	exo-bornyl...	58479-55-3	C14H24O2	
★	261-331-6	diethyl hyd...	58567-05-8	C8H14O5	
★	261-495-9	Heme a3	58916-42-0		
★	261-672-0	isodecyl pal...	59231-33-3	C26H52O2	
★	261-917-1	allyl glycinate	59765-55-8	C5H9NO2	
★	261-921-3	N6-(1-oxo...	59766-99-3	C16H32N2...	
★	262-329-8	2,3,5-trichl...	60613-17-4	C8H8Cl3NS	
★	262-520-6	1-ethyl-1,3...	60899-29-8	C14H20	

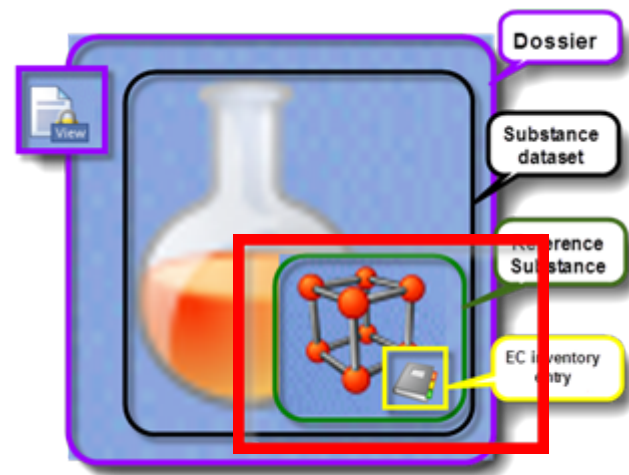
Number of limited results: 2000

Assign Close

Understand the structure



Give the identifier. Wildcards as * can be used



Understand the structure



REFERENCE SUBSTANCE: REFERENCE SUBSTANCE X

General information

Reference substance name: Reference Substance X

EC inventory

EC number: 261-281-5 CAS number: 58479-55-3

EC name: exo-bornyl butyrate

Molecular formula: C14H24O2

Description:

No EC information available

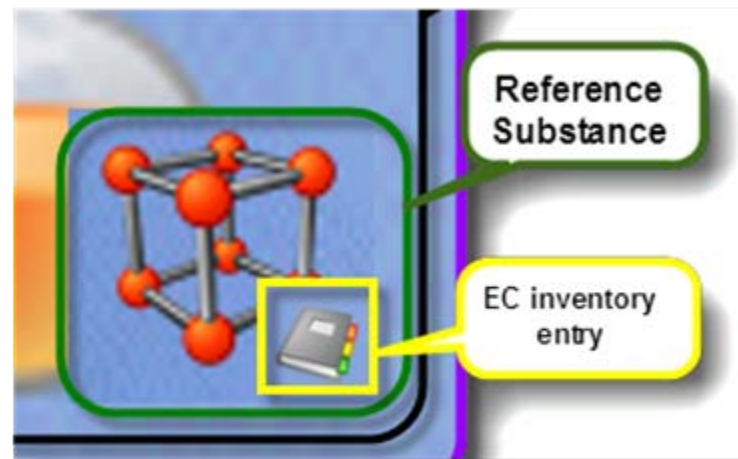
Justification:

Reference substance information

CAS information

CAS number: 58479-55-3

CAS name:

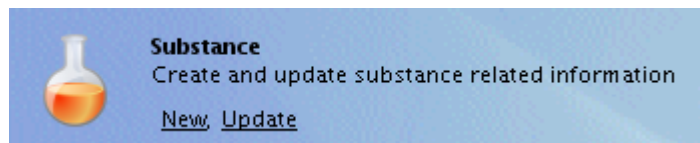


Substance dataset

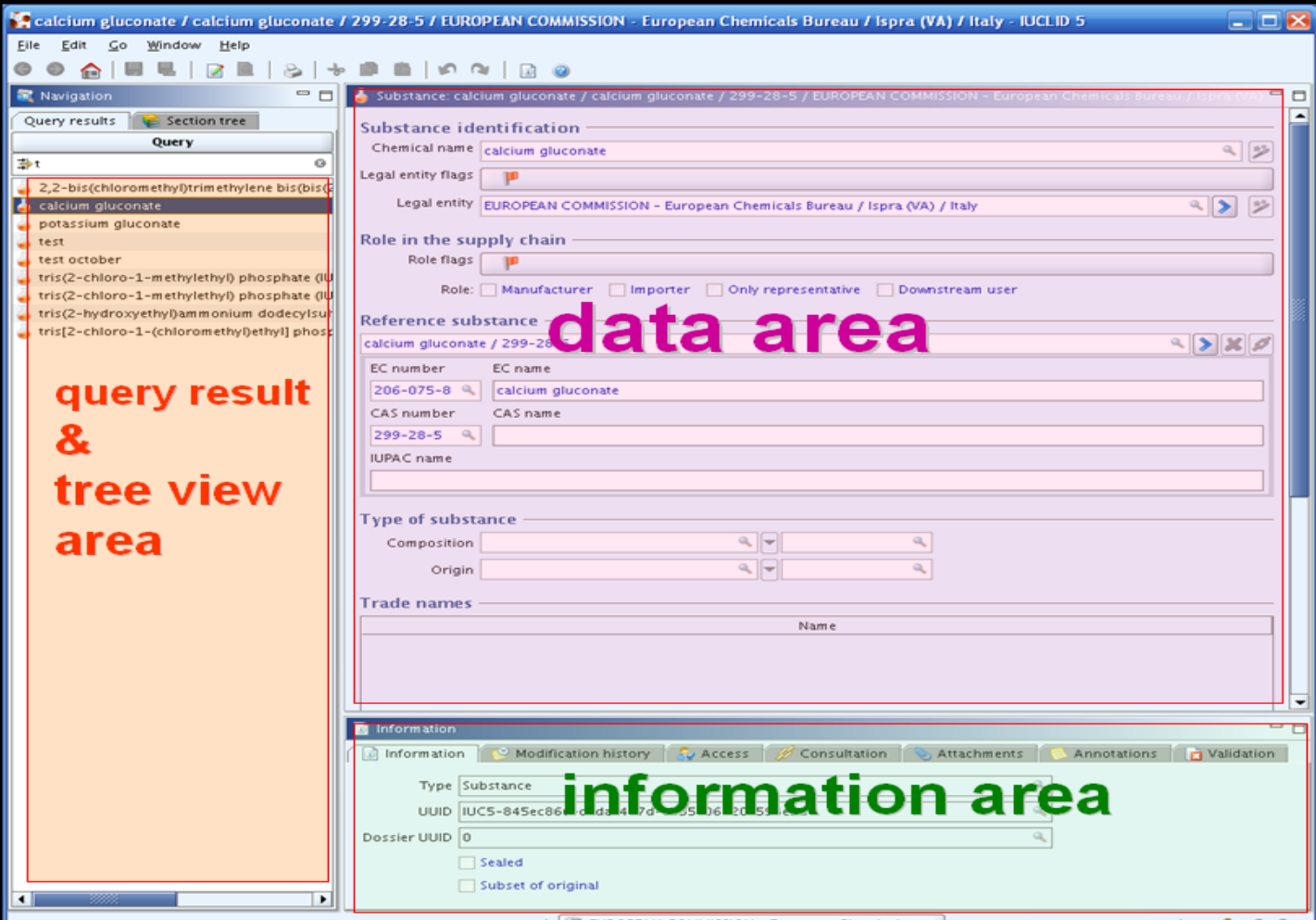


What is a substance dataset

- 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 interface



The screenshot displays the ECHA Substance dataset interface. On the left, a navigation pane shows a query result tree with 'calcium gluconate' selected. The main area is divided into two sections:

- query result & tree view area** (highlighted in orange): This section contains the navigation pane and the query results list.
- data area** (highlighted in pink): This section contains the detailed substance information form, including fields for chemical name, legal entity, role in the supply chain, reference substance, and type of substance.

The detailed substance information form includes the following fields:

- Substance identification:** Chemical name (calcium gluconate), Legal entity flags, Legal entity (EUROPEAN COMMISSION - European Chemicals Bureau / Ispra (VA) / Italy).
- Role in the supply chain:** Role flags, Role (Manufacturer, Importer, Only representative, Downstream user).
- Reference substance:** calcium gluconate / 299-28-5.
- EC number:** 206-075-8, EC name: calcium gluconate.
- CAS number:** 299-28-5, CAS name.
- IUPAC name:**
- Type of substance:** Composition, Origin.
- Trade names:** Name.

At the bottom, the **information area** (highlighted in green) shows the following details:

- Information:** Type (Substance), Modification history, Access, Consultation, Attachments, Annotations, Validation.
- Type:** Substance
- UUID:** IUUCS-845ec86-c0-d0-4-7d-0-35-06-20-5
- Dossier UUID:** 0
- Sealed:**
- Subset of original:**

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.

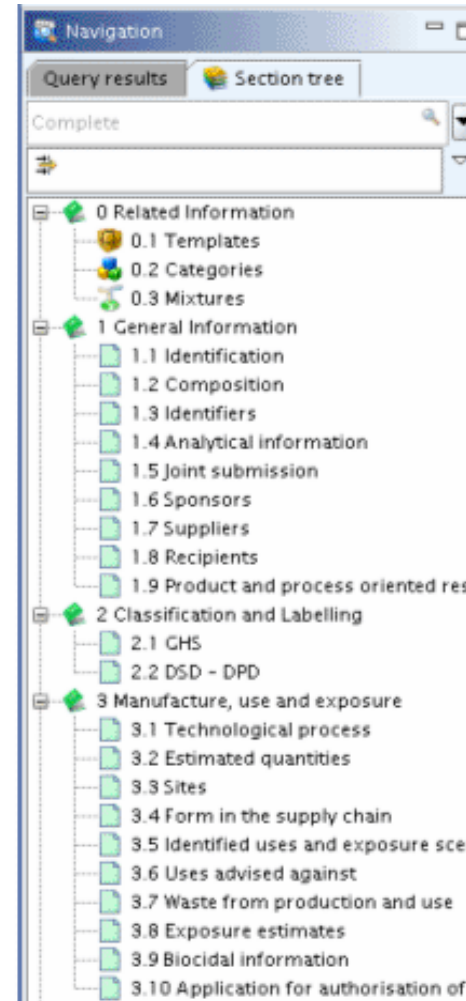
When a Substance dataset is exported or a Dossier is created out of it, everything connected to the root element is always included.

Section 0

Section 2



Section 1






















Section 3



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**

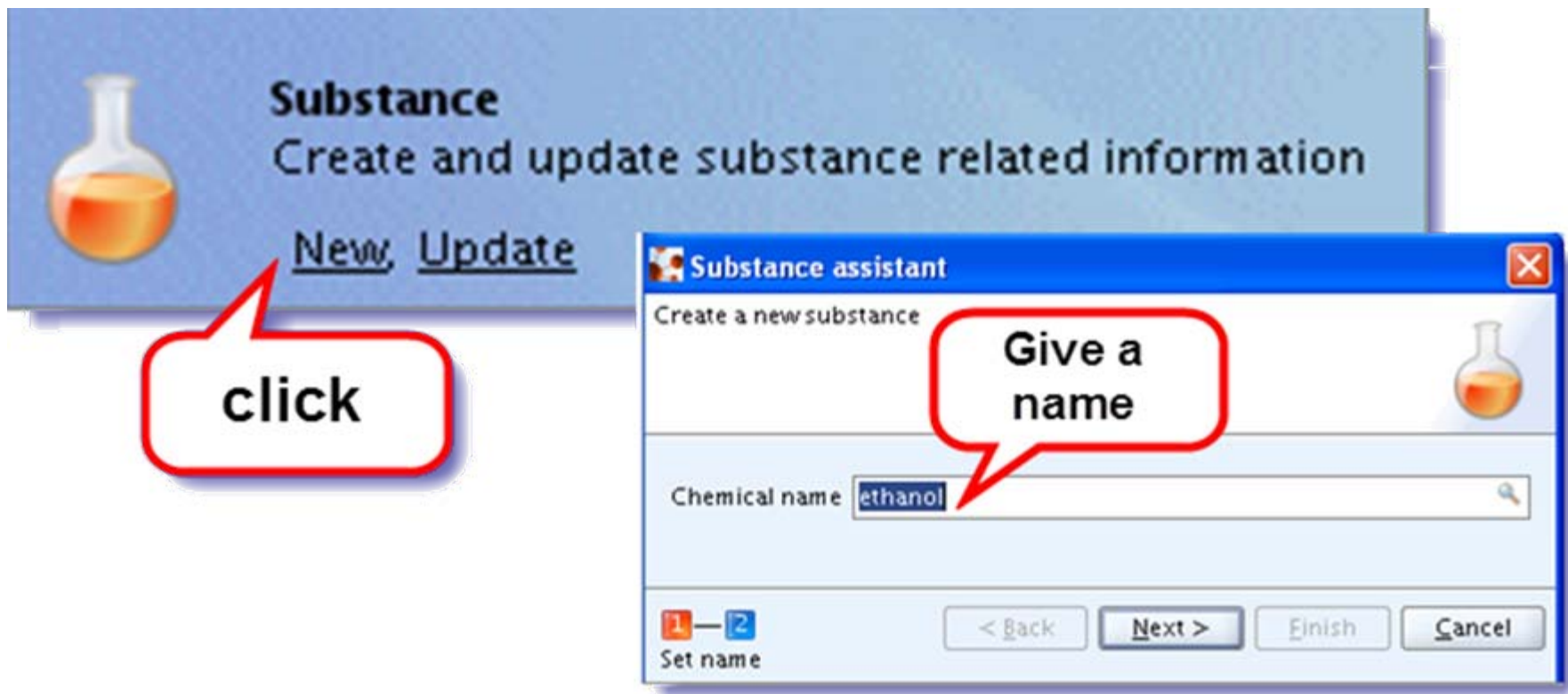
-   4 Physical and chemical properties
-   5 Environmental fate and pathways
-   6 Ecotoxicological Information
-   7 Toxicological information
-   8 Analytical methods
-   9 Residues in food and feedingstuffs
-   10 Effectiveness against target organisms
-   11 Guidance on safe use
-   12 Literature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



Basic functionalities on substance datasets



How to create a Substance dataset



Substance
Create and update substance related information

New, Update

click

Substance assistant
Create a new substance

Give a name

Chemical name

1 — 2
Set name

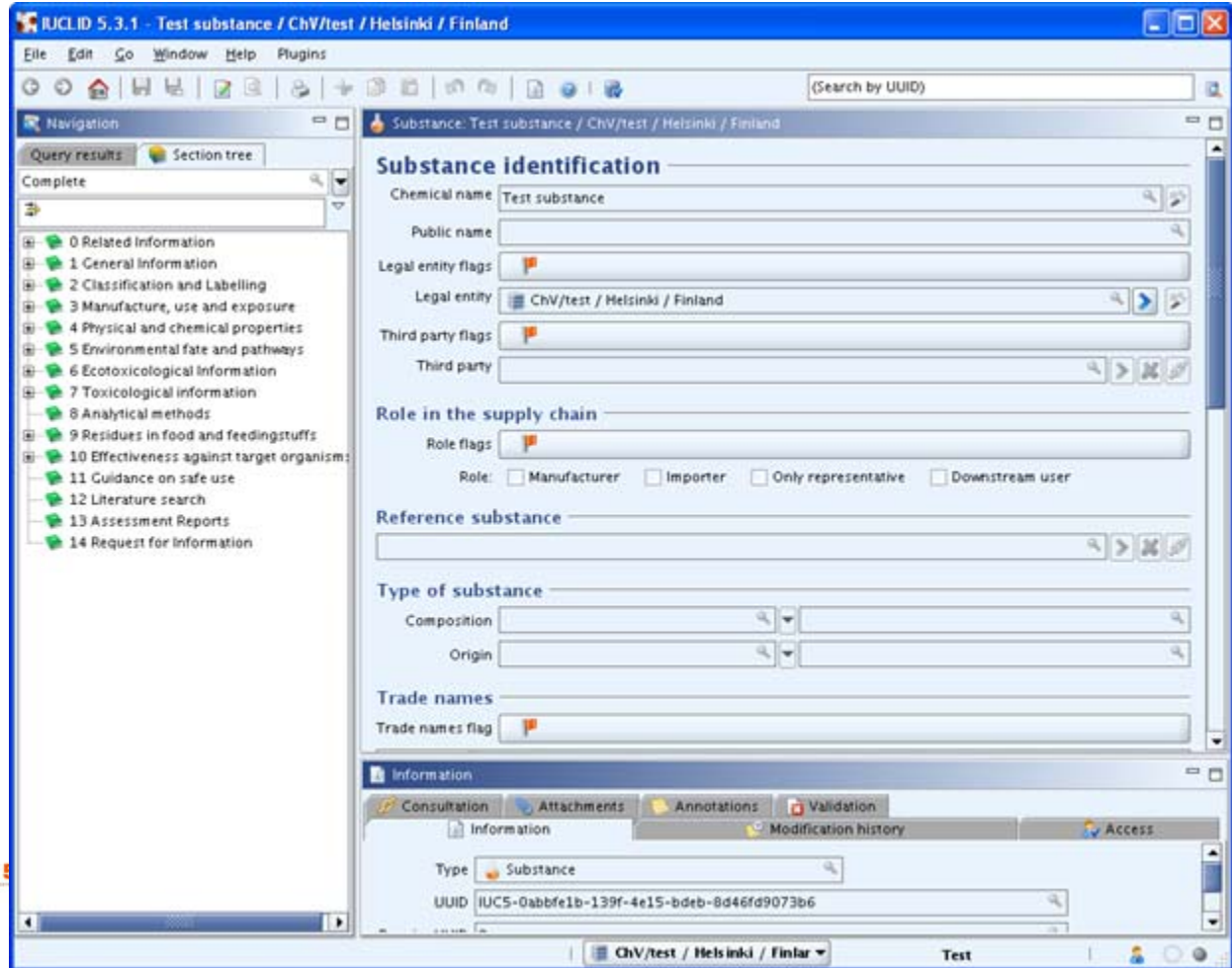
< Back Next > Finish Cancel

How to create a Substance dataset



Click the  button.

Tree view of a substance- now what?



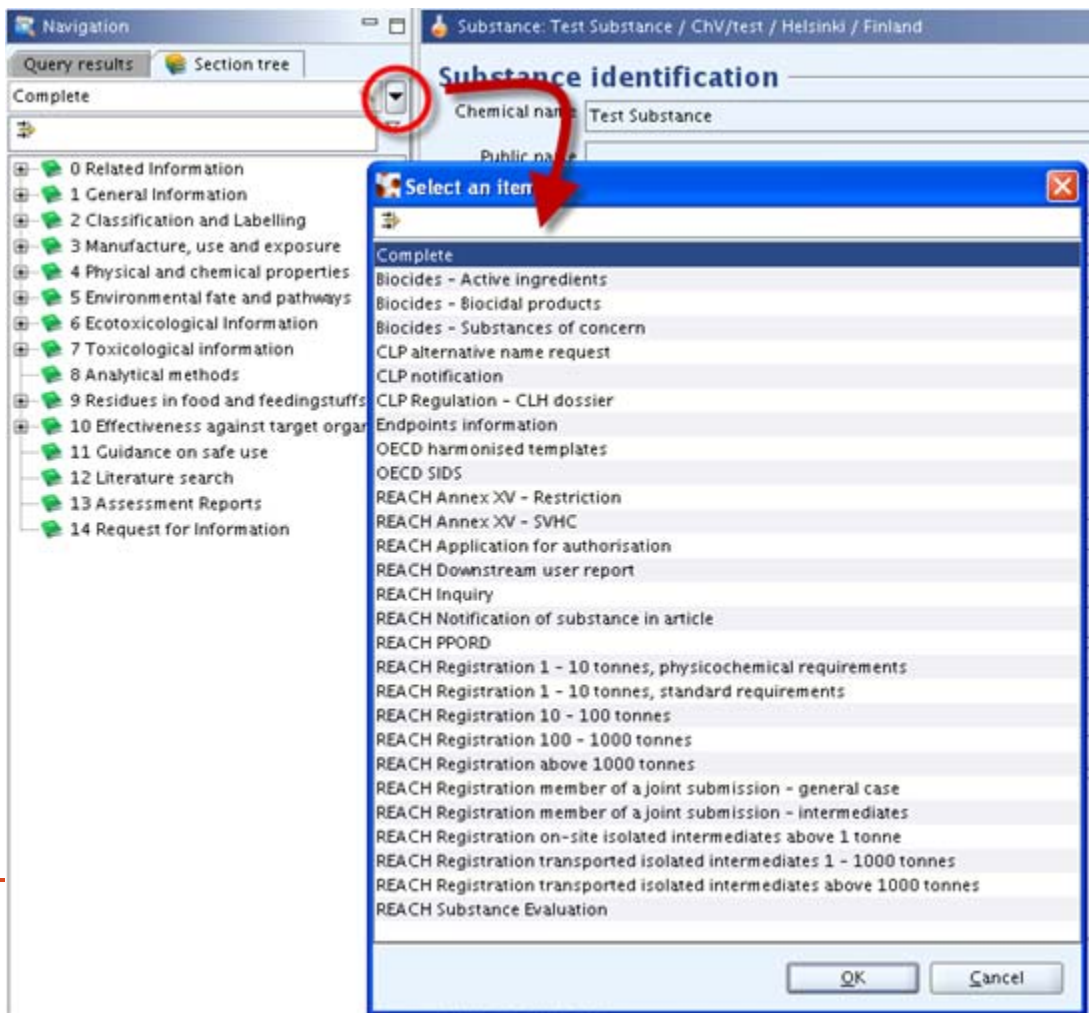
The screenshot displays the IUCLID 5.3.1 software interface. The window title is "IUCLID 5.3.1 - Test substance / ChV/test / Helsinki / Finland". The interface is divided into several panes:

- Navigation Pane (Left):** Shows a "Section tree" with 15 categories, each with a green icon and a plus sign. The categories are: 0 Related Information, 1 General Information, 2 Classification and Labelling, 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 Residues in food and feedingstuffs, 10 Effectiveness against target organisms, 11 Guidance on safe use, 12 Literature search, 13 Assessment Reports, and 14 Request for Information.
- Main Content Area (Right):** Displays "Substance identification" and "Role in the supply chain" information.
 - Substance identification:** Includes fields for "Chemical name" (Test substance), "Public name", "Legal entity flags" (with a red flag icon), "Legal entity" (ChV/test / Helsinki / Finland), "Third party flags" (with a red flag icon), and "Third party".
 - Role in the supply chain:** Includes "Role flags" (with a red flag icon) and a "Role" section with radio buttons for "Manufacturer", "Importer", "Only representative", and "Downstream user".
 - Reference substance:** A field for entering a reference substance.
 - Type of substance:** Includes "Composition" and "Origin" dropdown menus.
 - Trade names:** Includes a "Trade names flag" (with a red flag icon).
- Information Pane (Bottom):** Shows tabs for "Consultation", "Attachments", "Annotations", and "Validation". The "Information" tab is active, displaying "Type" (Substance) and "UUID" (IUC5-0abbfe1b-139f-4e15-bdeb-8d46fd9073b6).



How to select a template

- Click on the black arrow
- Select the appropriate template



The screenshot displays the ECHA Substance Identification interface. The main window shows a 'Substance identification' section for 'Test Substance' with a 'Chemical name' field. A 'Section tree' on the left lists 14 categories, with '10 Effectiveness against target organ' selected. A 'Select an item' dialog box is open, showing a list of templates. A red circle highlights a black arrow icon in the top-left corner of the dialog box, and a red arrow points from this icon to the 'Select an item' dialog box.

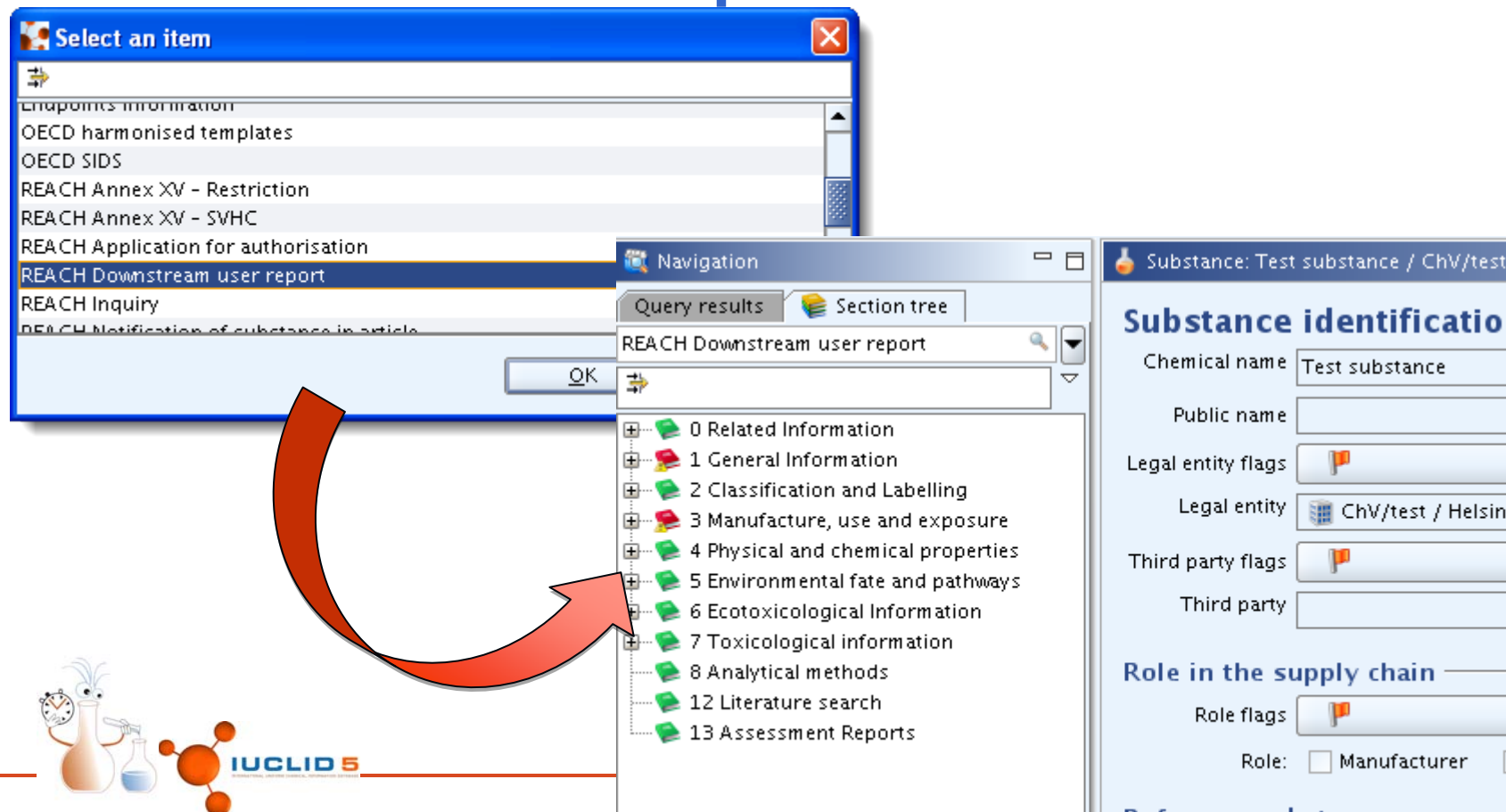
Select an item

Complete

- Biocides - Active ingredients
- Biocides - Biocidal products
- Biocides - Substances of concern
- CLP alternative name request
- CLP notification
- CLP Regulation - CLH dossier
- Endpoints information
- OECD harmonised templates
- OECD SIDS
- REACH Annex XV - Restriction
- REACH Annex XV - SVHC
- REACH Application for authorisation
- REACH Downstream user report
- REACH Inquiry
- REACH Notification of substance in article
- 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
- REACH Registration on-site isolated intermediates above 1 tonne
- REACH Registration transported isolated intermediates 1 - 1000 tonnes
- REACH Registration transported isolated intermediates above 1000 tonnes
- REACH Substance Evaluation

OK Cancel

Example- template Downstream Users report



The screenshot illustrates the process of selecting a template in IUCLID 5. A 'Select an item' dialog box is shown with 'REACH Downstream user report' selected. This leads to a 'Navigation' window displaying a 'Section tree' for the chosen report type. A large red arrow points from the selected item in the dialog to the corresponding section in the tree.

Select an item

- Endpoints information
- OECD harmonised templates
- OECD SIDS
- REACH Annex XV - Restriction
- REACH Annex XV - SVHC
- REACH Application for authorisation
- REACH Downstream user report**
- REACH Inquiry
- REACH Notification of substance in article

Navigation

Query results | Section tree

REACH Downstream user report

- 0 Related Information
- 1 General Information
- 2 Classification and Labelling
- 3 Manufacture, use and exposure
- 4 Physical and chemical properties
- 5 Environmental fate and pathways
- 6 Ecotoxicological Information
- 7 Toxicological information
- 8 Analytical methods
- 12 Literature search
- 13 Assessment Reports

Substance: Test substance / ChV/test

Substance identification

Chemical name: Test substance

Public name: []

Legal entity flags: []

Legal entity: ChV/test / Helsin

Third party flags: []

Third party: []

Role in the supply chain

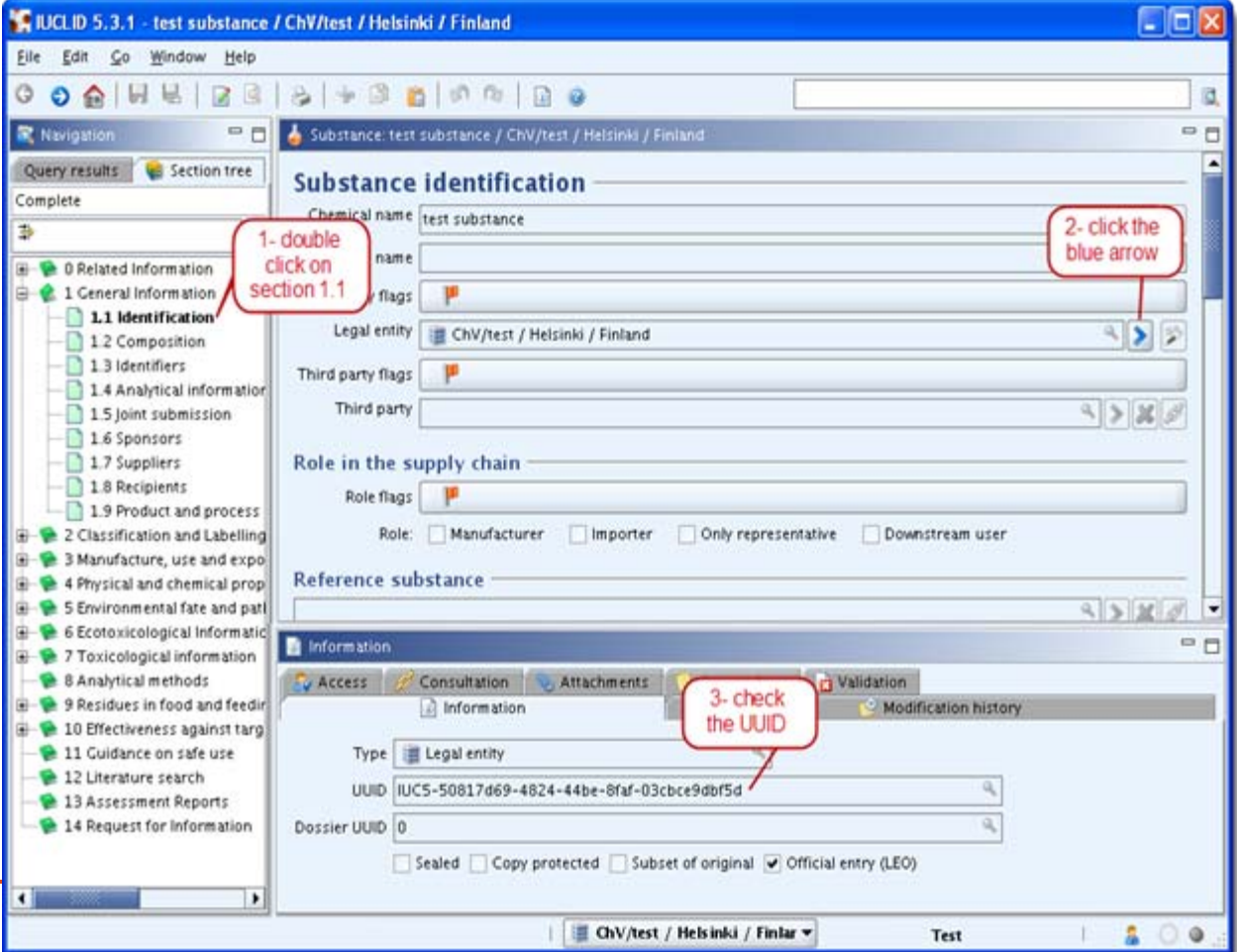
Role flags: []

Role: Manufacturer



How to check the legal entity in section 1.1

- Double click on section 1.1
- Click the blue arrow (Legal entity)
- Check the UUID (Information panel)



IUCLID 5.3.1 - test substance / ChV/test / Helsinki / Finland

File Edit Go Window Help

Navigation Substance: test substance / ChV/test / Helsinki / Finland

Query results Section tree

Complete

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

1.9 Product and process

2 Classification and Labelling

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 Residues in food and feed

10 Effectiveness against target

11 Guidance on safe use

12 Literature search

13 Assessment Reports

14 Request for information

Substance identification

Chemical name: test substance

name: []

flags: []

Legal entity: ChV/test / Helsinki / Finland [blue arrow]

Third party flags: []

Third party: []

Role in the supply chain

Role flags: []

Role: Manufacturer Importer Only representative Downstream user

Reference substance

[]

Information

Access Consultation Attachments Validation

Information Modification history

Type: Legal entity

UUID: IUCS-50817d69-4824-44be-8faf-03cbce9dbf5d

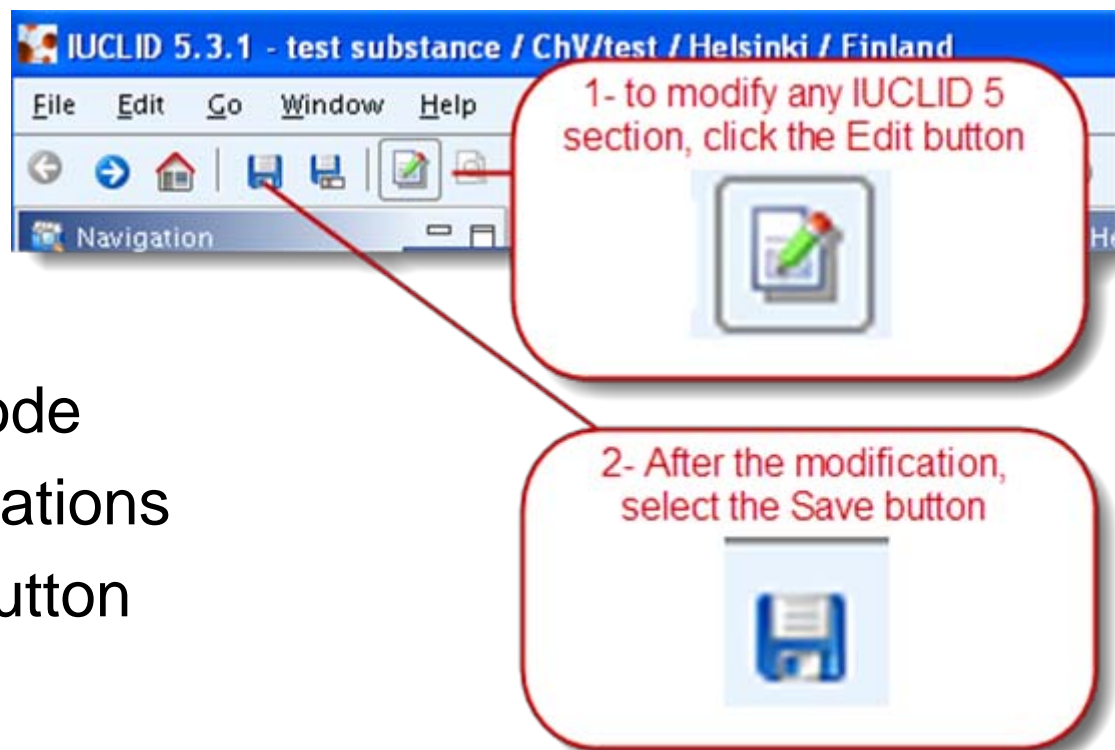
Dossier UUID: 0

Sealed Copy protected Subset of original Official entry (LEO)

ChV/test / Helsinki / Finland Test

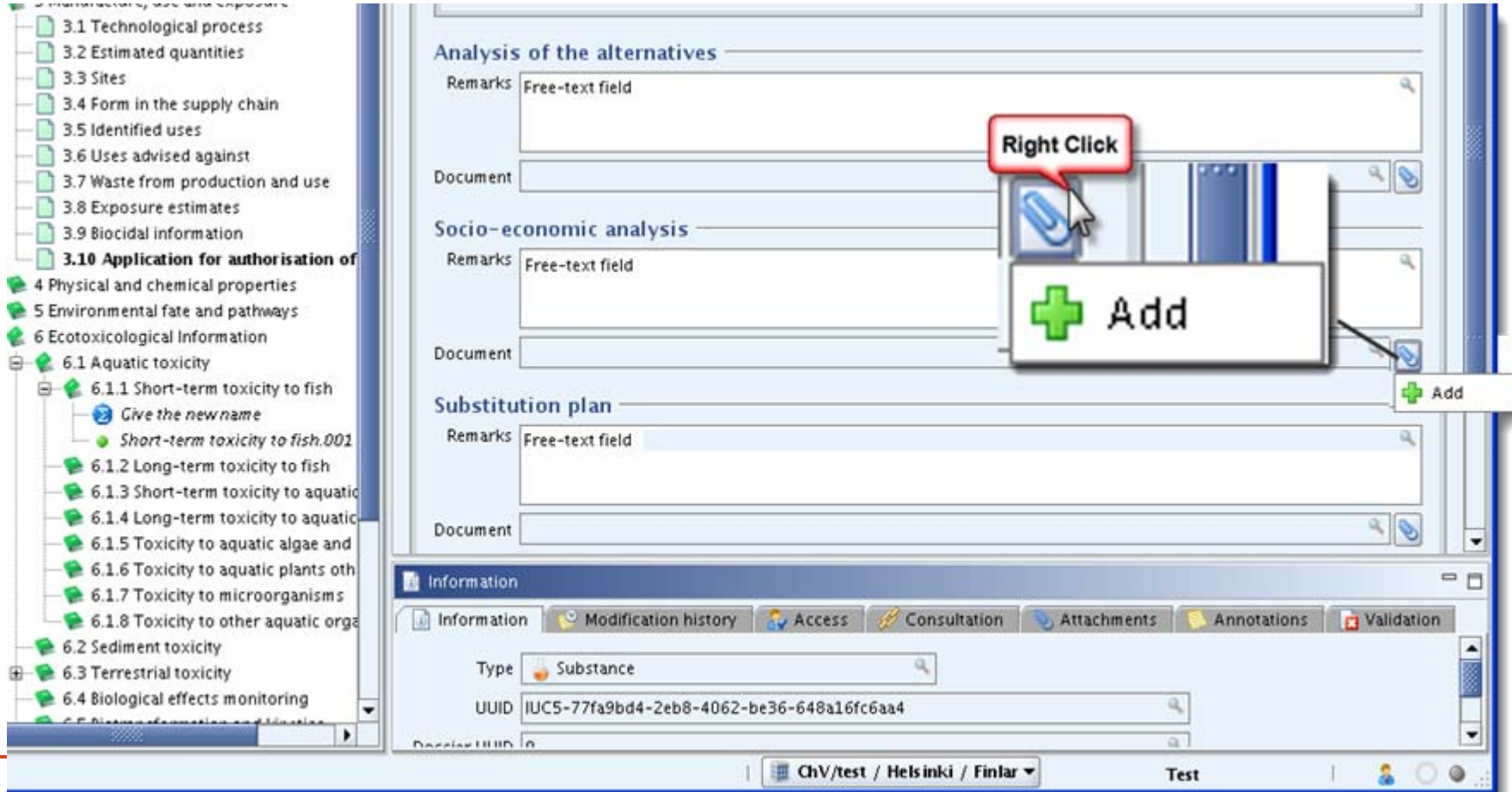


How to modify a IUCLID 5 section



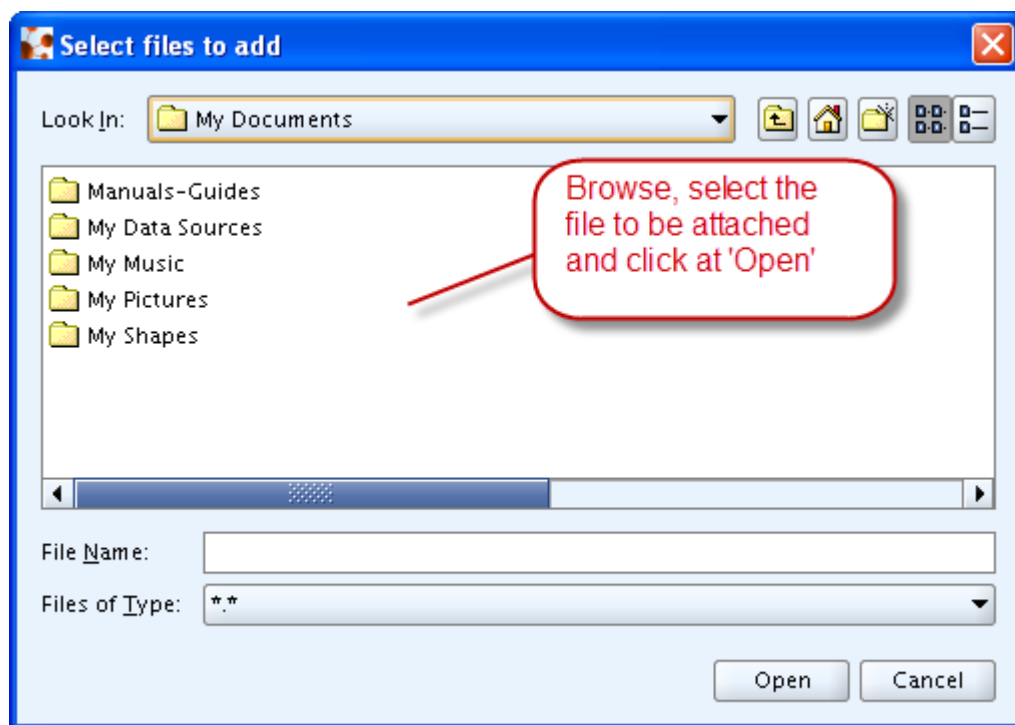
- Click on 'edit' mode
- Edit your modifications
- Click on 'save' button

How to attach a file into a IUCLID section

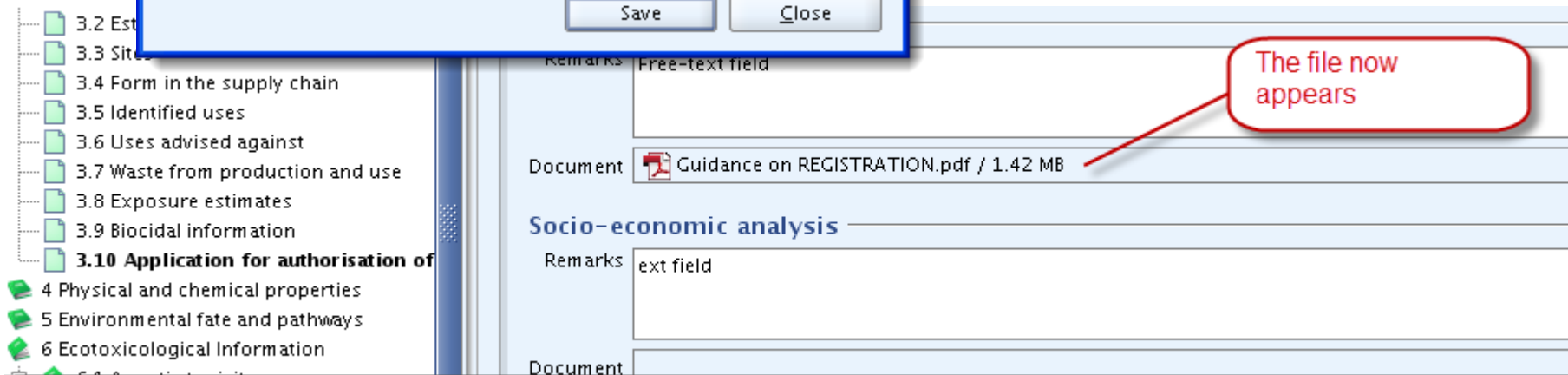
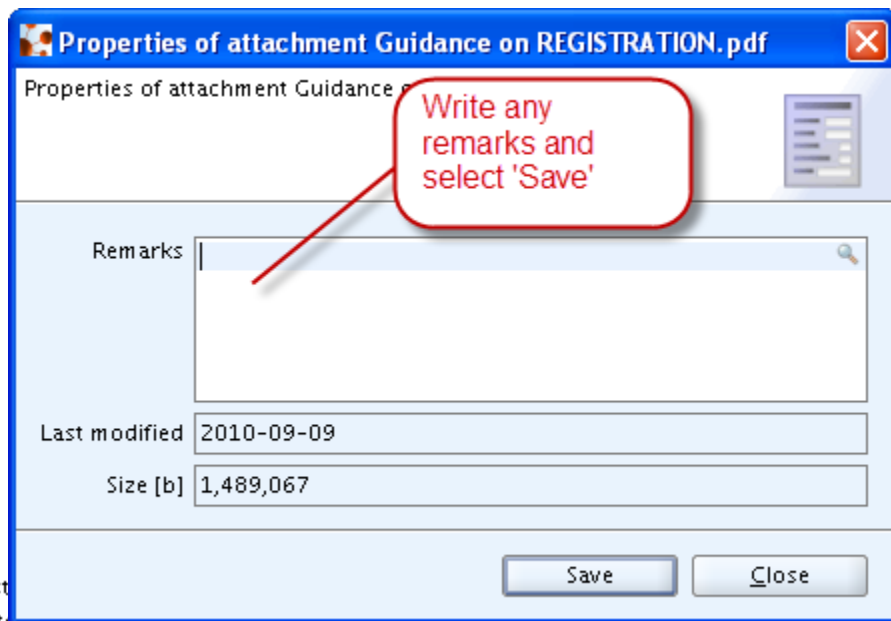


The screenshot displays the IUCLID software interface. On the left is a tree view of sections, with '3.10 Application for authorisation of' selected. The main area shows three sections: 'Analysis of the alternatives', 'Socio-economic analysis', and 'Substitution plan'. Each section has a 'Remarks' field and a 'Document' field. A red callout bubble labeled 'Right Click' points to a paperclip icon in the 'Document' field of the 'Socio-economic analysis' section. A context menu is open, showing a green plus sign and the word 'Add'. Another 'Add' button is visible in the bottom right corner of the 'Document' field. At the bottom, an 'Information' panel shows details for a 'Substance' with UUID 'IUC5-77fa9bd4-2eb8-4062-be36-648a16fc6aa4'. The status bar at the very bottom reads 'ChV/test / Helsinki / Finlar' and 'Test'.

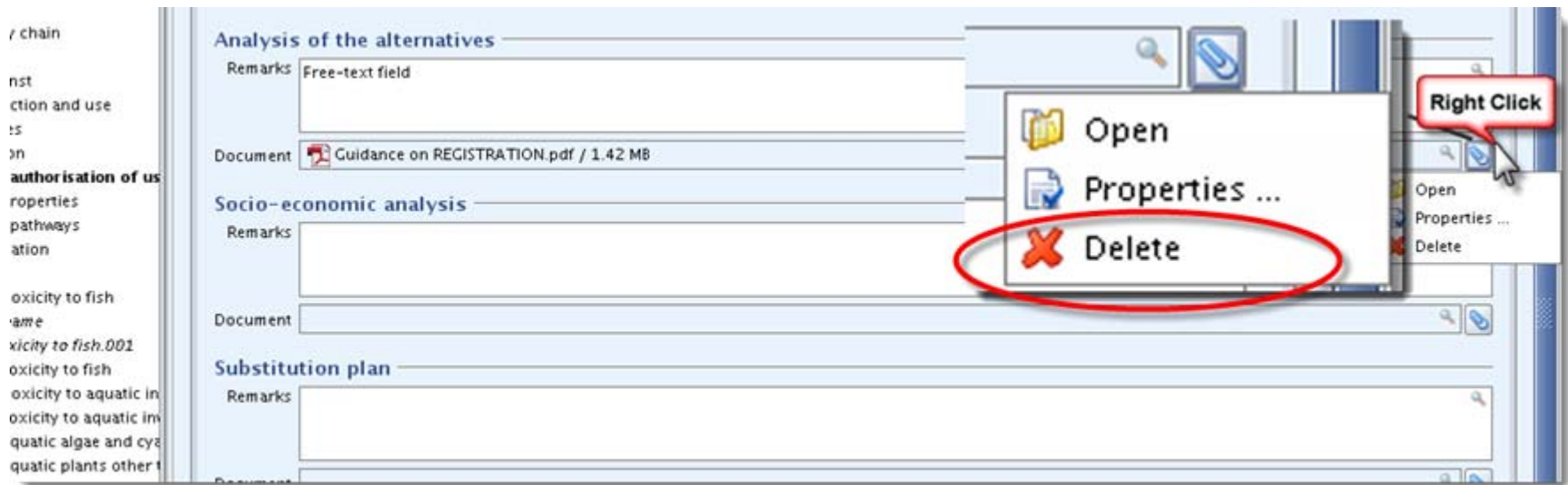
How to attach a file into a IUCLID section



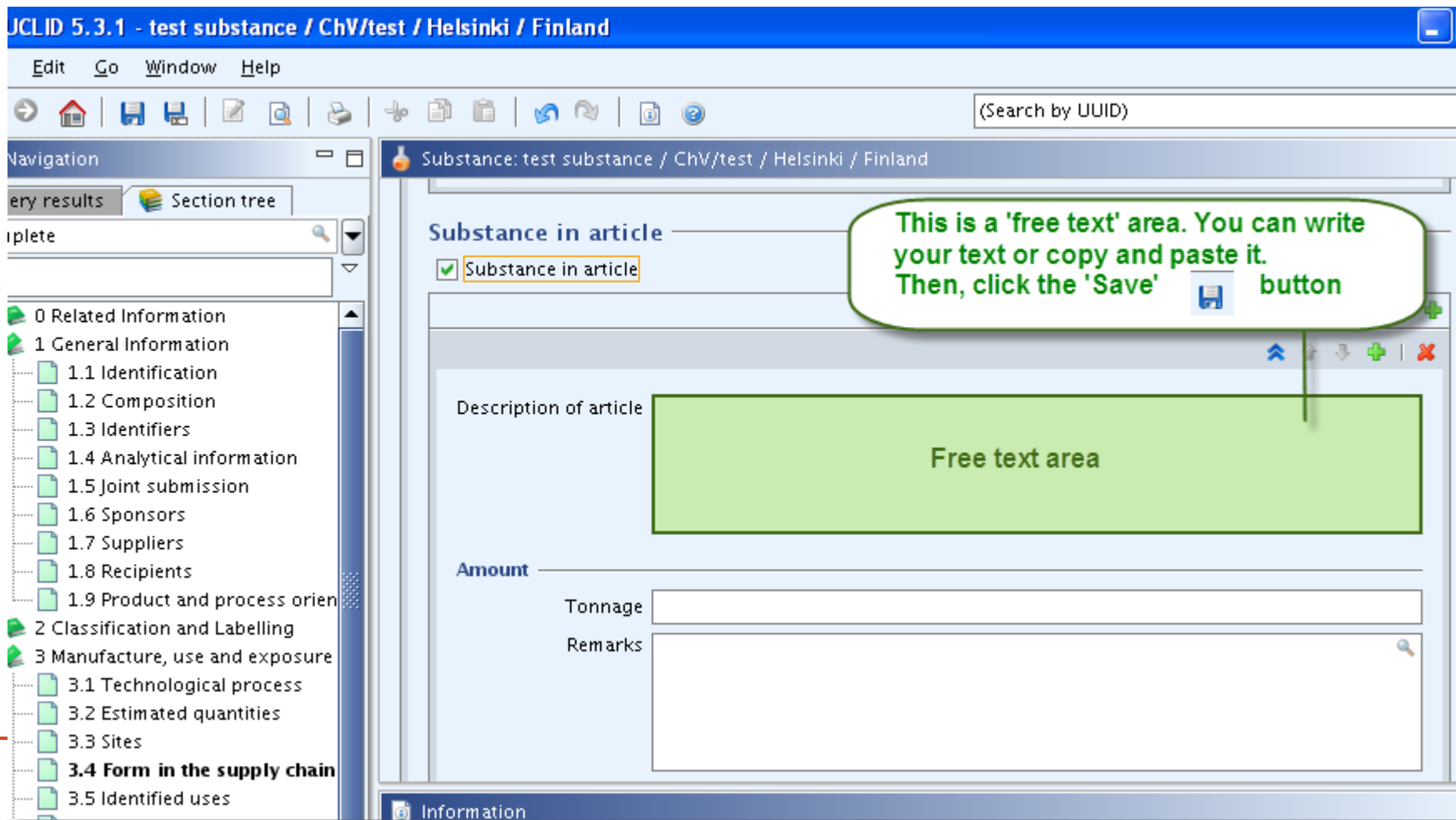
How to attach a file into a IUCLID section



How to remove an attachment from a IUCLID section



How to enter data in 'free text' fields



JCLID 5.3.1 - test substance / ChV/test / Helsinki / Finland

Edit Go Window Help

(Search by UUID)

Navigation

Query results Section tree

Complete

- 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
 - 1.9 Product and process orientation
- 2 Classification and Labelling
- 3 Manufacture, use and exposure
 - 3.1 Technological process
 - 3.2 Estimated quantities
 - 3.3 Sites
 - 3.4 Form in the supply chain**
 - 3.5 Identified uses

Substance: test substance / ChV/test / Helsinki / Finland

Substance in article

Substance in article

Description of article

Free text area

Amount

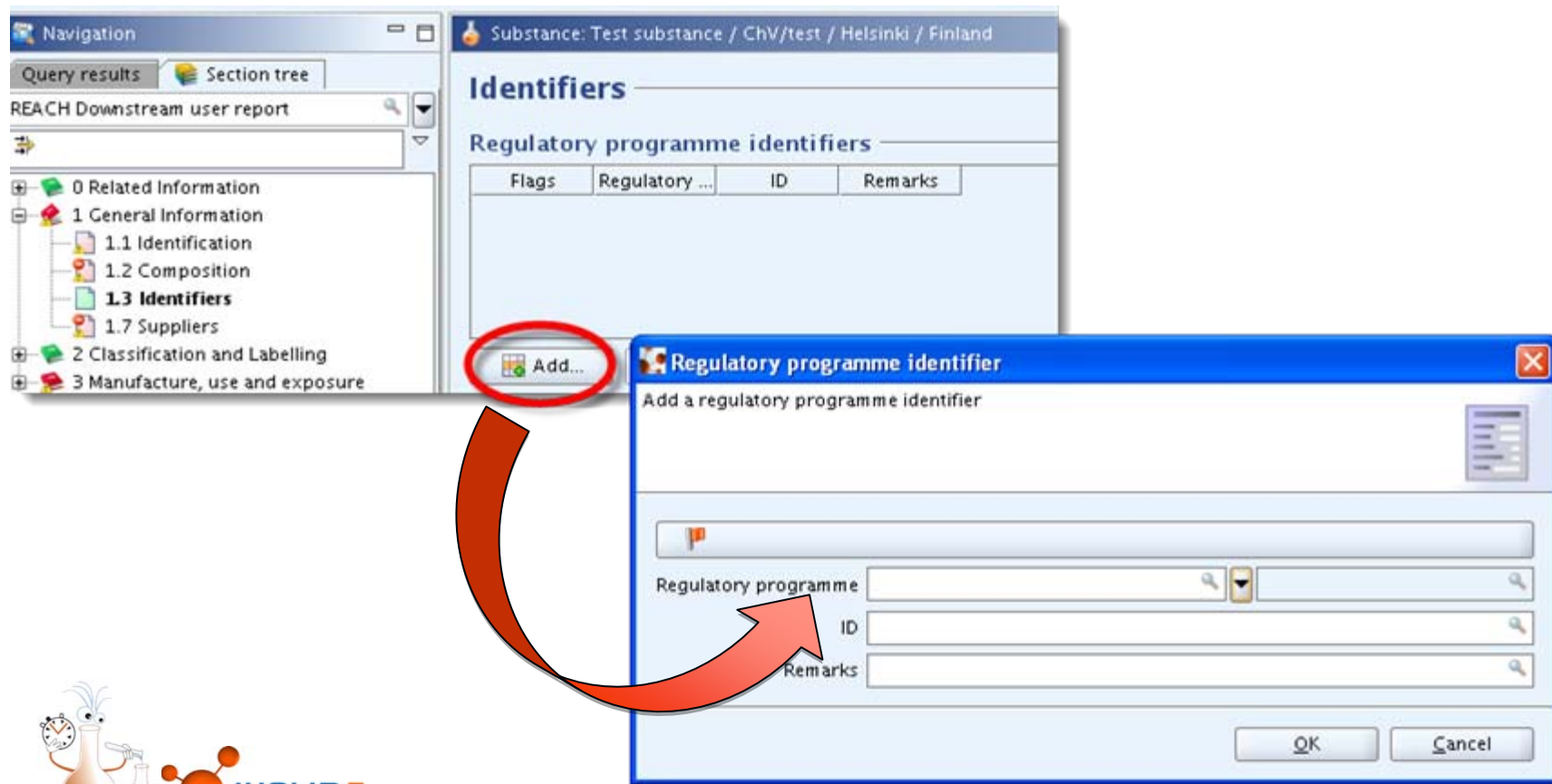
Tonnage

Remarks

Information

This is a 'free text' area. You can write your text or copy and paste it. Then, click the 'Save' button

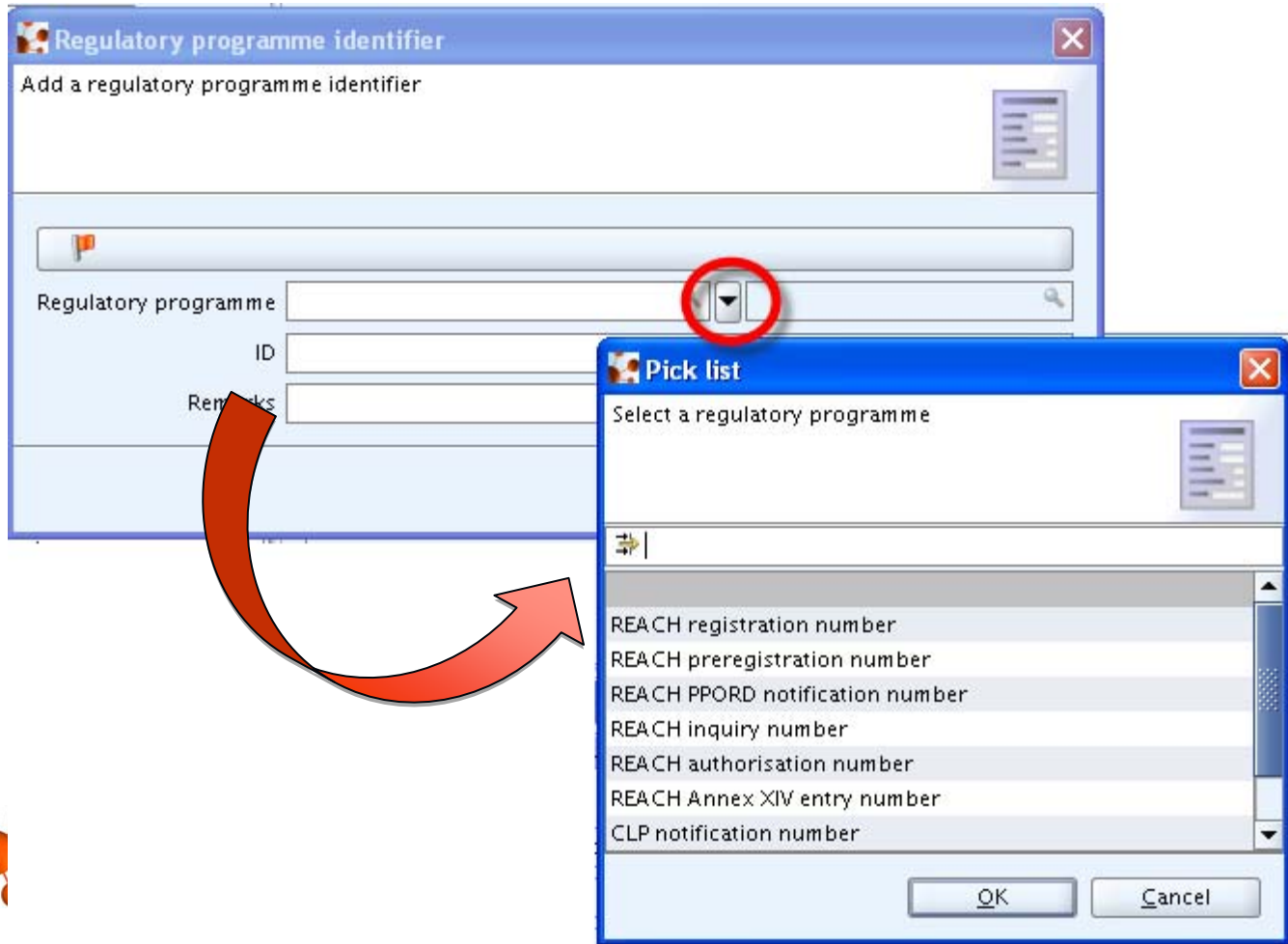
How to enter data in '+Add' button



The screenshot shows the ECHA REACH database interface. On the left is a navigation pane with a tree view containing sections like '0 Related Information', '1 General Information', '1.1 Identification', '1.2 Composition', '1.3 Identifiers', '1.7 Suppliers', '2 Classification and Labelling', and '3 Manufacture, use and exposure'. The main area displays 'Substance: Test substance / ChV/test / Helsinki / Finland' and 'Identifiers'. Under 'Regulatory programme identifiers', there is a table with columns 'Flags', 'Regulatory ...', 'ID', and 'Remarks'. A red circle highlights the '+Add...' button in the table. A red arrow points from this button to a modal dialog titled 'Regulatory programme identifier'. The dialog contains a search bar, a dropdown menu for 'Regulatory programme', and input fields for 'ID' and 'Remarks'. 'OK' and 'Cancel' buttons are at the bottom.



How to enter data in '+Add' button



Regulatory programme identifier
Add a regulatory programme identifier

Regulatory programme

ID

Remarks

Pick list
Select a regulatory programme

- REACH registration number
- REACH preregistration number
- REACH PPORD notification number
- REACH inquiry number
- REACH authorisation number
- REACH Annex XIV entry number
- CLP notification number

OK Cancel






How to enter data in '+Add' button

Substance: Test substance / ChV/test / Helsinki / Finland

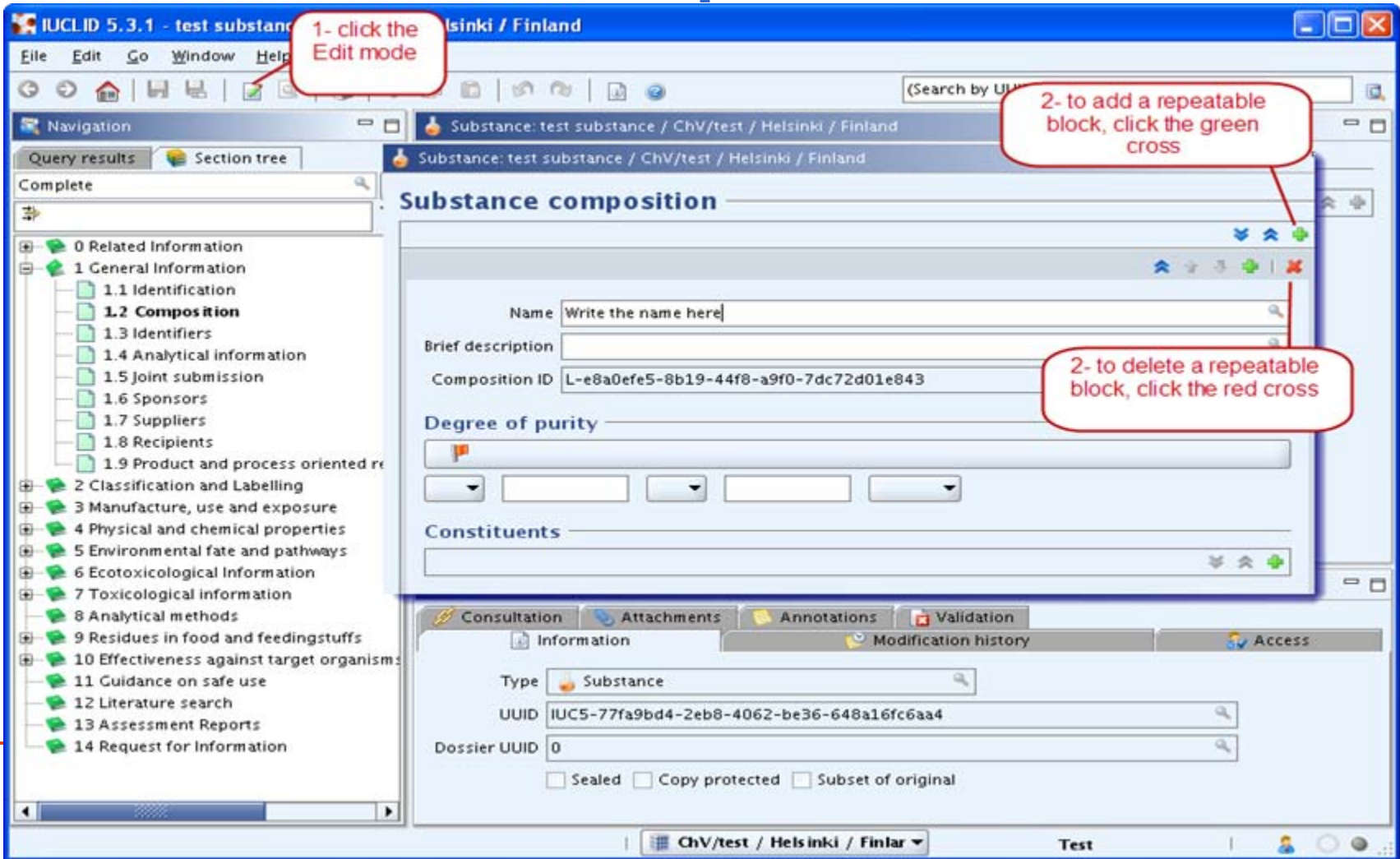
Identifiers

Regulatory programme identifiers

Flags	Regulatory programme	ID	Remarks
	REACH registration number	01-XXXXXXXXXX-CC-0000	

 Add...  Edit...  Delete

How to handle the repeatable blocks



The screenshot displays the IUCLID 5.3.1 software interface for managing test substances. The main window is titled "Substance: test substance / ChV/test / Helsinki / Finland". The left sidebar shows a "Section tree" with 14 categories, including "1.2 Composition". The main content area is titled "Substance composition" and contains several input fields: "Name" (with placeholder "Write the name here"), "Brief description", and "Composition ID" (with value "L-e8a0efe5-8b19-44f8-a9f0-7dc72d01e843"). Below these is a "Degree of purity" section with a dropdown menu and a "Constituents" section with a list box. At the bottom, there are tabs for "Consultation", "Attachments", "Annotations", and "Validation", with sub-tabs for "Information", "Modification history", and "Access". The "Information" sub-tab is active, showing fields for "Type" (Substance), "UUID" (IUUC5-77fa9bd4-2eb8-4062-be36-648a16fc6aa4), and "Dossier UUID" (0). There are also checkboxes for "Sealed", "Copy protected", and "Subset of original".

1- click the Edit mode

2- to add a repeatable block, click the green cross

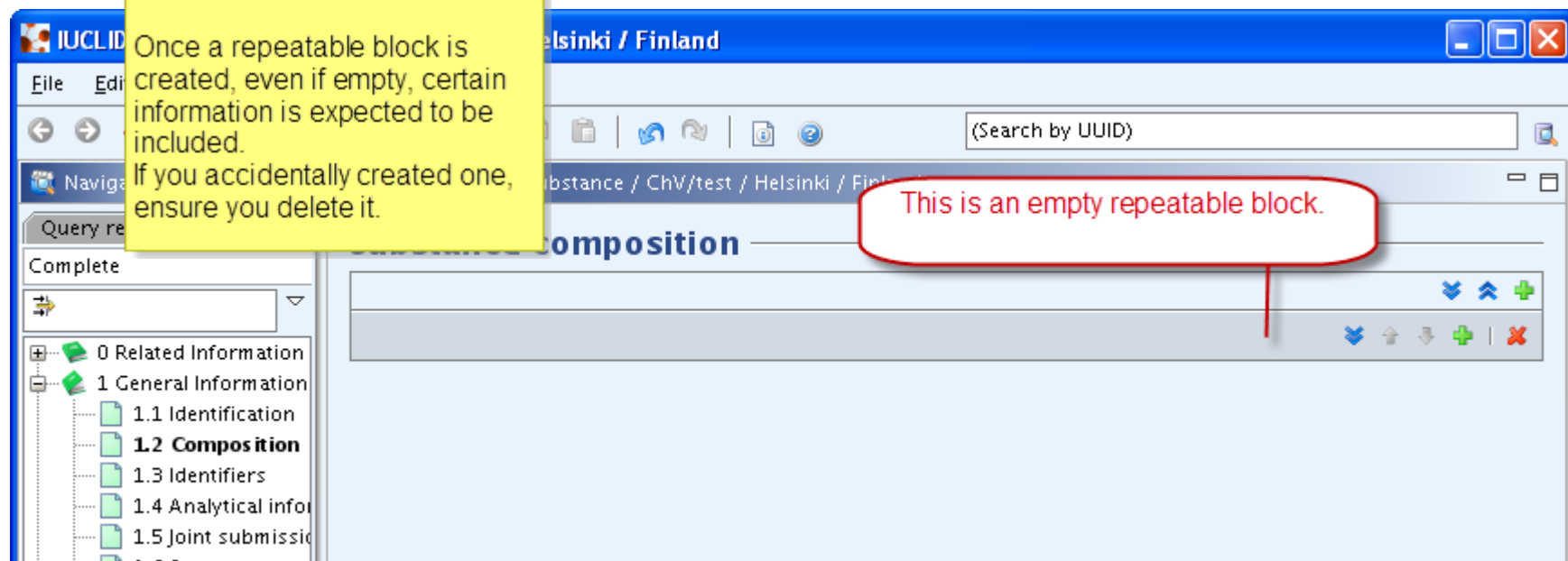
2- to delete a repeatable block, click the red cross

How to handle the repeatable blocks

Tip:

Once a repeatable block is created, even if empty, certain information is expected to be included.

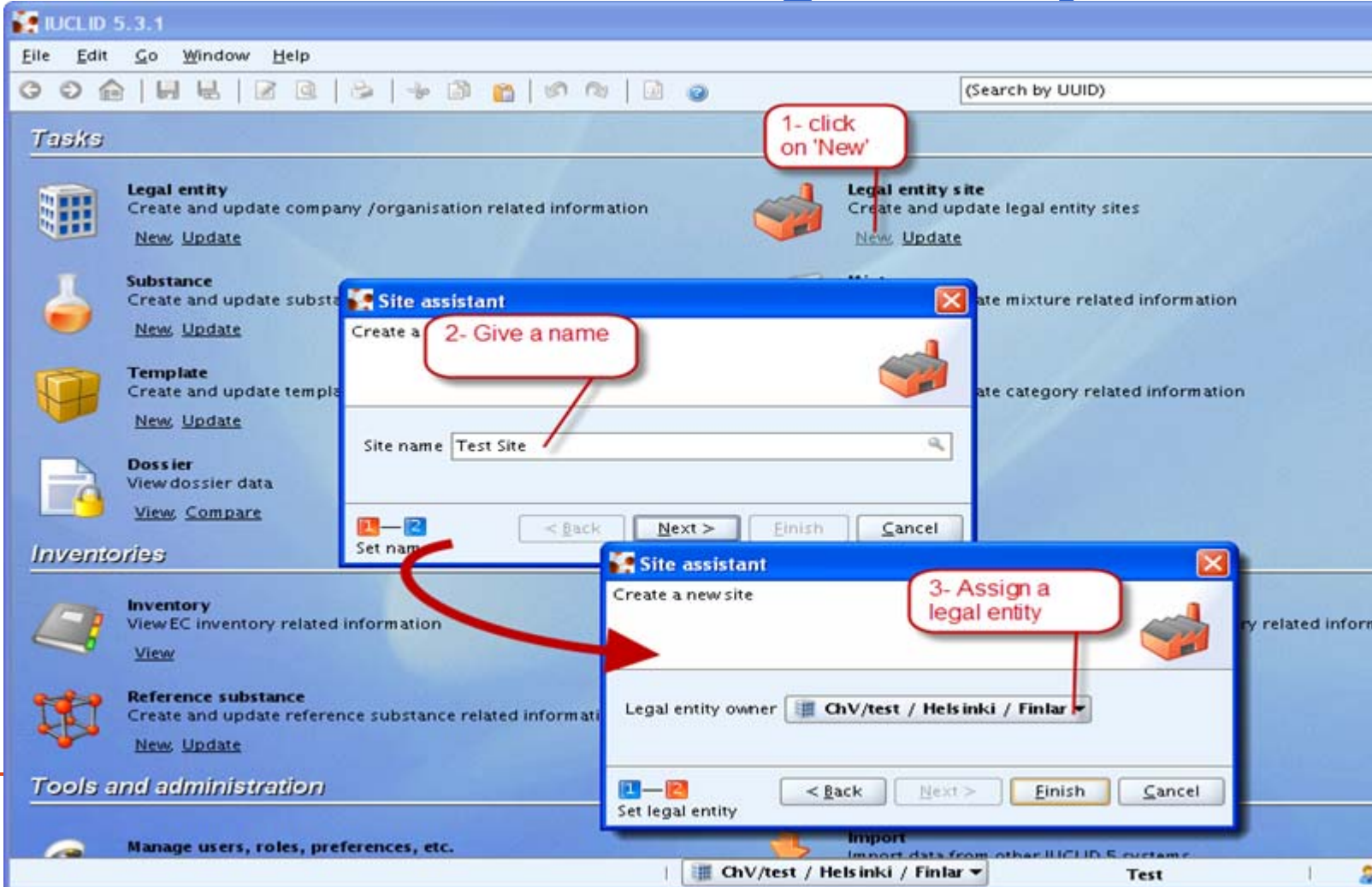
If you accidentally created one, ensure you delete it.



The screenshot shows the IUCLID 5 software interface. The main window displays a 'Composition' block. A red callout box points to an empty row in the composition table, stating 'This is an empty repeatable block.' The left sidebar shows a tree view with '1.2 Composition' selected. The top navigation bar includes a search box labeled '(Search by UUID)' and a breadcrumb trail: 'Substance / ChV/test / Helsinki / Finland'.



How to create a new legal entity site



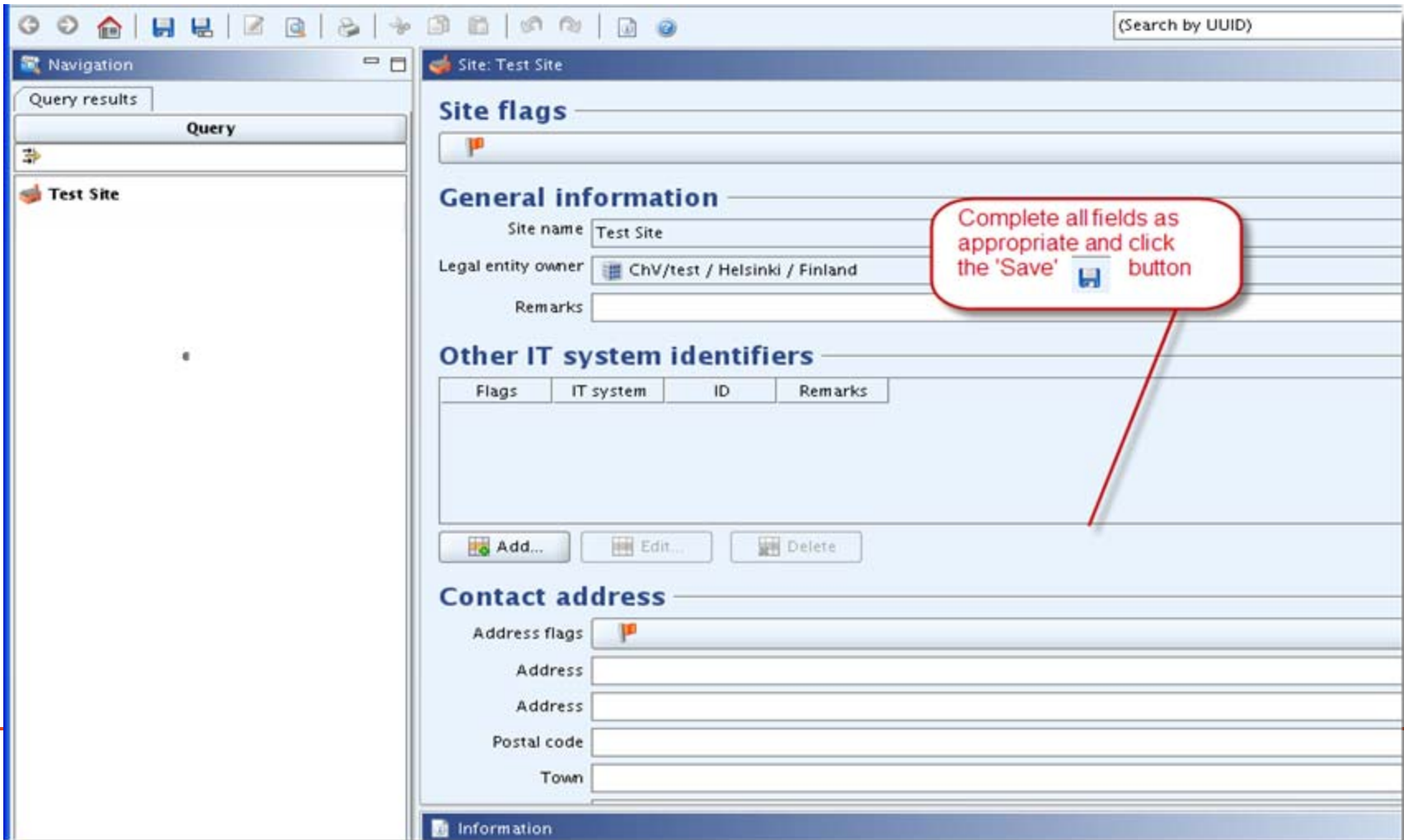
The screenshot displays the IUCLID 5.3.1 software interface. The main window shows a sidebar with categories: **Tasks** (Legal entity, Substance, Template, Dossier), **Inventories** (Inventory, Reference substance), and **Tools and administration** (Manage users, roles, preferences, etc.). The 'Legal entity site' task is highlighted with a red callout: "1- click on 'New'".

A 'Site assistant' dialog box is open, showing the 'Create a' step with a red callout: "2- Give a name". The 'Site name' field contains 'Test Site'. Below the field are buttons for '< Back', 'Next >', 'Finish', and 'Cancel'.

A second 'Site assistant' dialog box is open, showing the 'Set legal entity' step with a red callout: "3- Assign a legal entity". The 'Legal entity owner' dropdown menu is set to 'ChV/test / Helsinki / Finlar'. Below the dropdown are buttons for '< Back', 'Next >', 'Finish', and 'Cancel'.

At the bottom of the interface, the status bar shows 'ChV/test / Helsinki / Finlar' and 'Test'.

How to create a new legal entity site



(Search by UUID)

Navigation


Query results

Query

Test Site

Site: Test Site

Site flags



General information

Site name

Legal entity owner

Remarks

Other IT system identifiers

Flags	IT system	ID	Remarks
-------	-----------	----	---------

Contact address

Address flags


Address

Address

Postal code

Town

Information

Complete all fields as appropriate and click the 'Save'  button

Tip:

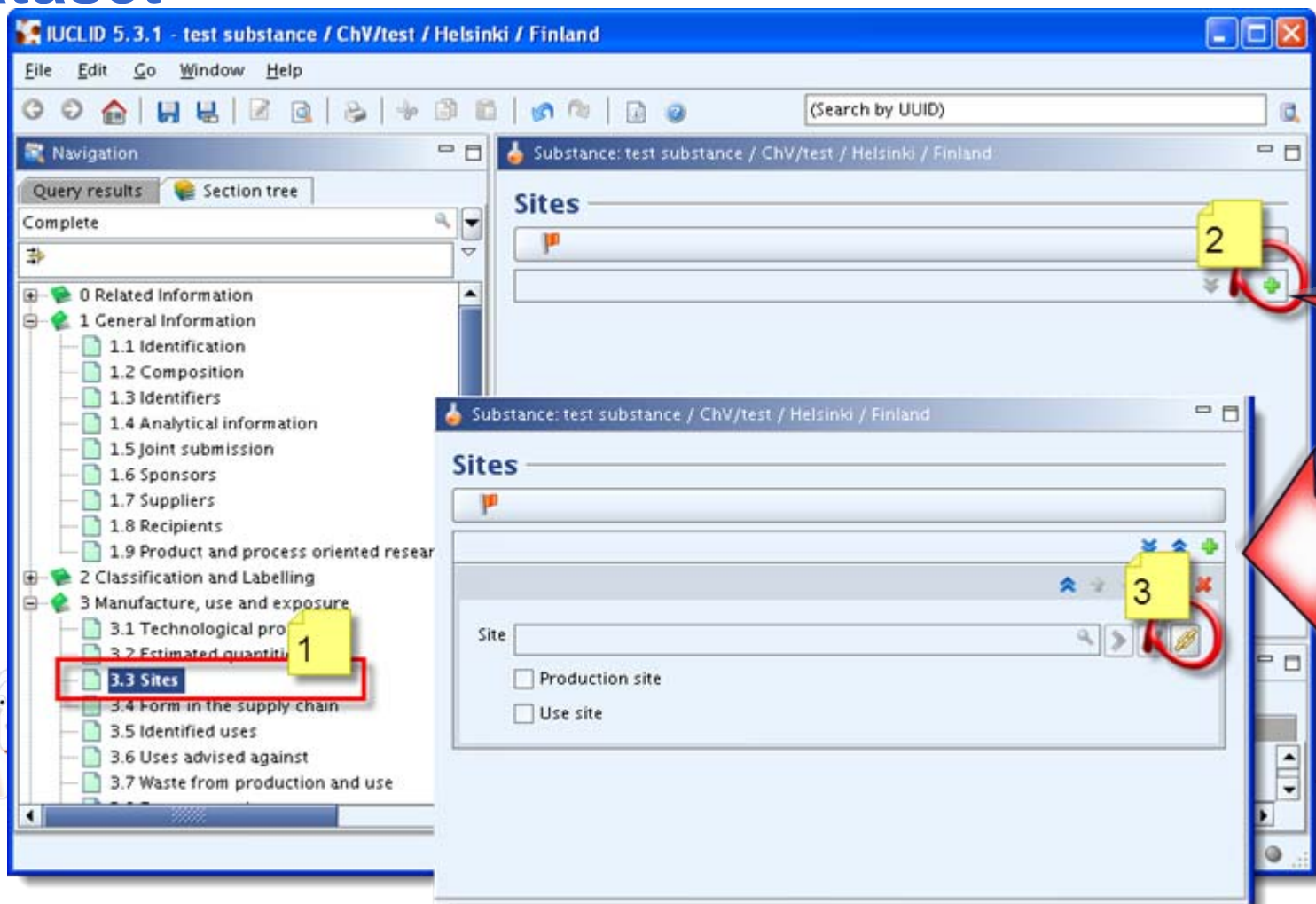
If you change your legal entity, the site you had in your substance dataset is dropped



Therefore you need to re-assign your site to your new legal entity

How to do that? see next

How to assign a new site to a substance dataset



The screenshot shows the IUCLID 5.3.1 software interface for a substance dataset. The window title is "IUCLID 5.3.1 - test substance / ChV/test / Helsinki / Finland". The interface includes a menu bar (File, Edit, Go, Window, Help), a toolbar, and a search box labeled "(Search by UUID)".

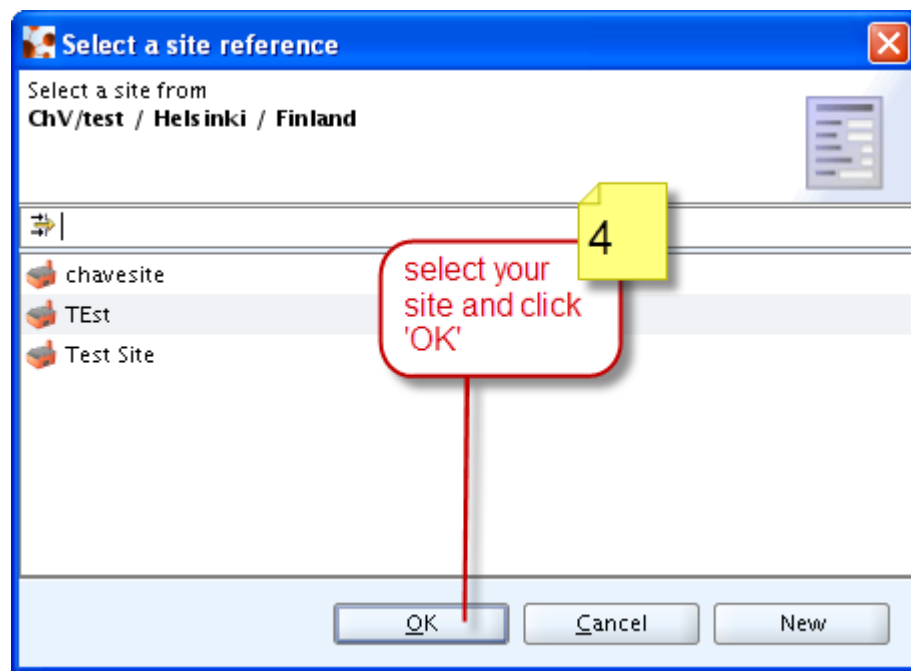
On the left, there is a "Navigation" pane with a "Section tree" view. The tree is expanded to show "3.3 Sites", which is highlighted with a red box and a yellow sticky note labeled "1".

The main area displays "Substance: test substance / ChV/test / Helsinki / Finland" and a "Sites" table. The table has one row with a flag icon. A yellow sticky note labeled "2" is placed over the "Add" (+) button in the table's toolbar.

A "Sites" dialog box is open in the foreground, also titled "Substance: test substance / ChV/test / Helsinki / Finland". It has a "Site" input field and two checkboxes: "Production site" and "Use site". A yellow sticky note labeled "3" is placed over the "Add" (+) button in the dialog's toolbar.

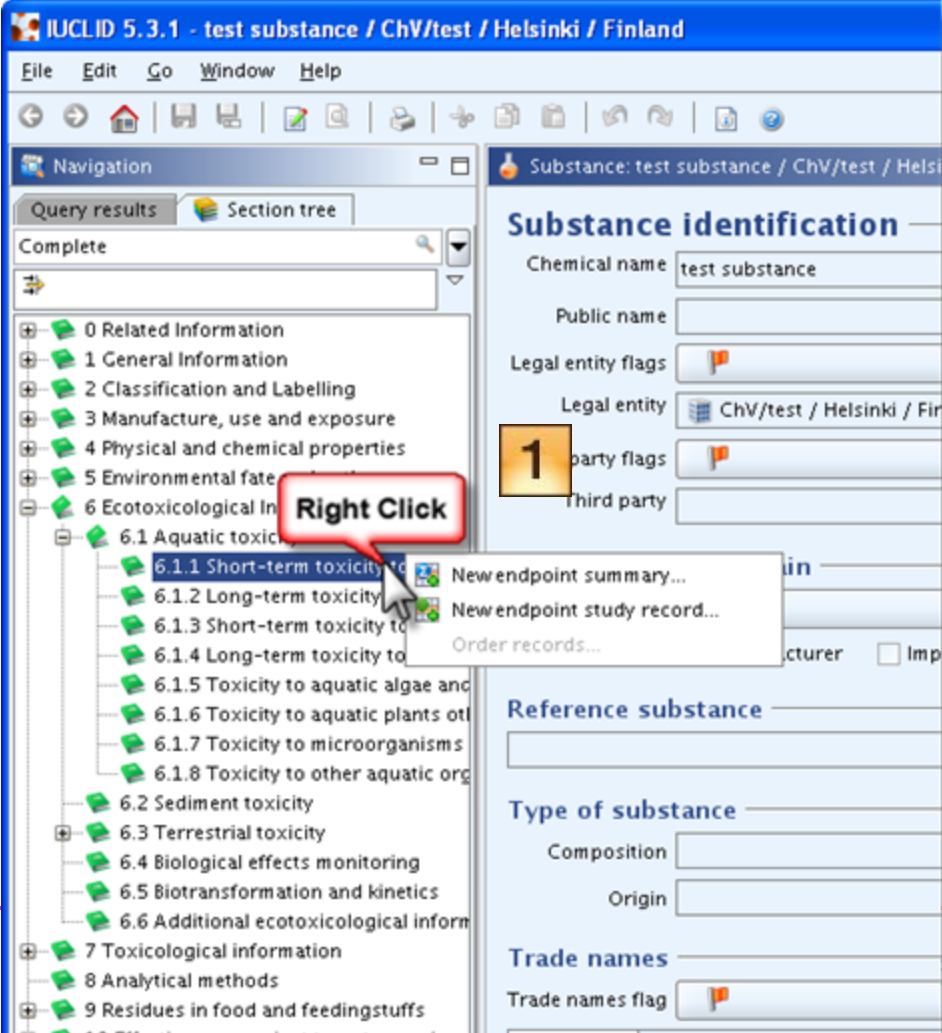
A large red arrow points from the "Add" button in the dialog box to the "Add" button in the main data entry area, indicating the flow of the process.

How to assign a new site to a substance dataset



How to add an endpoint

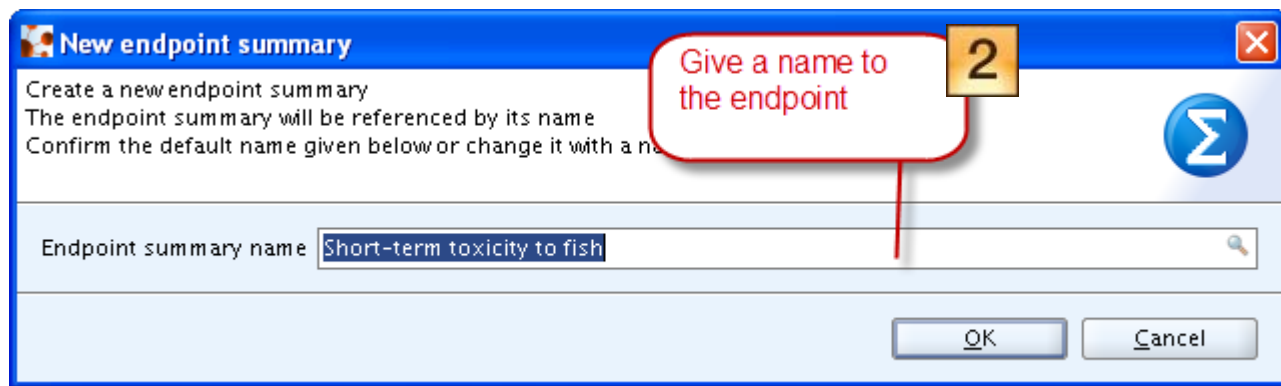
- Right click
- Select
‘New endpoint summary’
or
‘New endpoint study record’



The screenshot shows the IUCLID 5.3.1 interface for a test substance. The 'Section tree' on the left is expanded to '6.1 Aquatic toxicity', with '6.1.1 Short-term toxicity to aquatic invertebrates' selected. A right-click context menu is open, showing options: 'New endpoint summary...', 'New endpoint study record...', and 'Order records...'. A red callout box labeled 'Right Click' points to the menu. The right-hand pane shows 'Substance identification' fields: Chemical name (test substance), Public name, Legal entity flags, Legal entity (ChV/test / Helsinki / Finland), party flags (1), and Third party.



How to add an endpoint



New endpoint summary

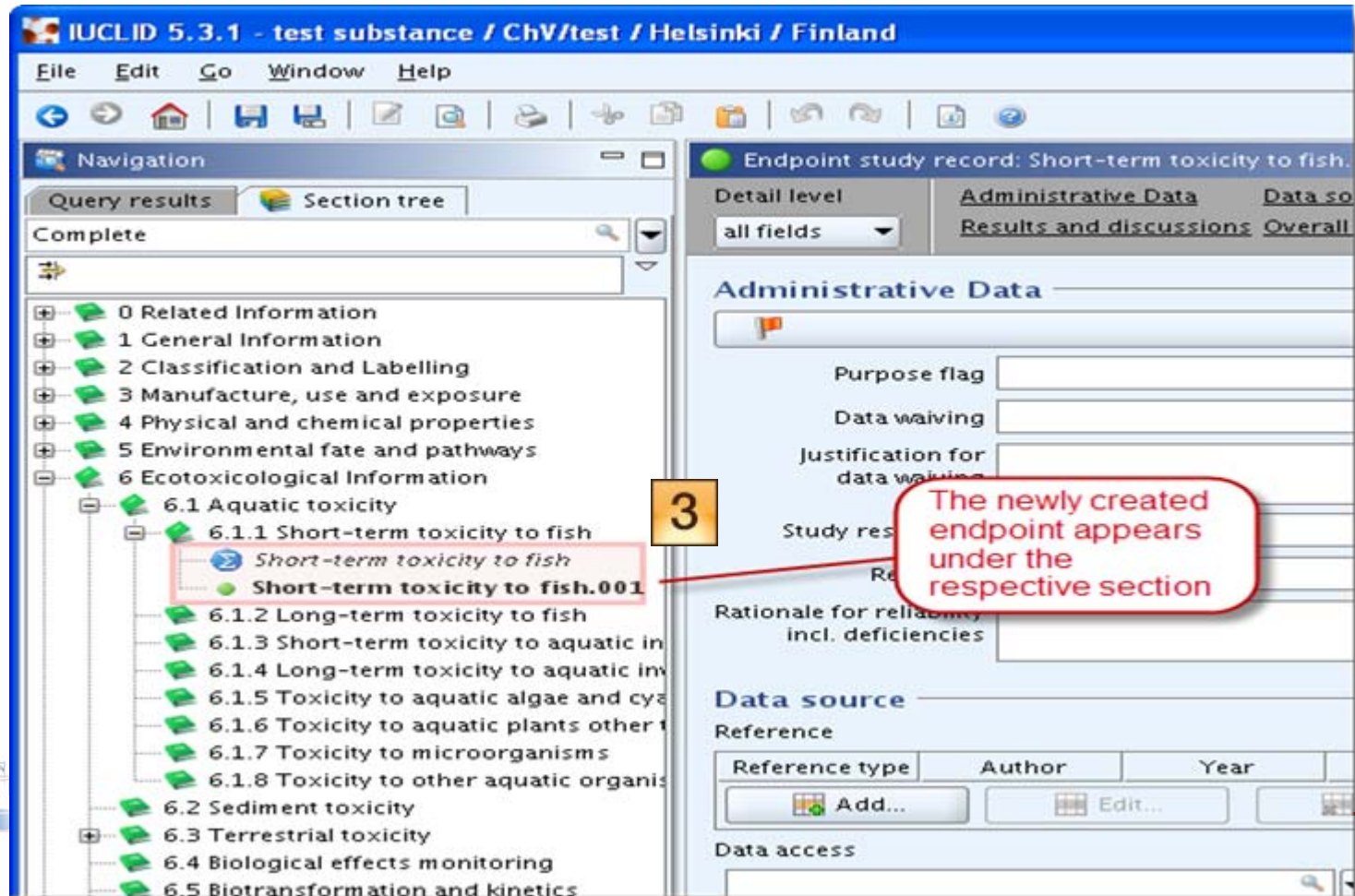
Create a new endpoint summary
The endpoint summary will be referenced by its name
Confirm the default name given below or change it with a name

Endpoint summary name

OK Cancel

Give a name to the endpoint

How to add an endpoint



IUCLID 5.3.1 - test substance / ChV/test / Helsinki / Finland

File Edit Go Window Help

Navigation

Query results Section tree

Complete

- 0 Related Information
- 1 General Information
- 2 Classification and Labelling
- 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
 - Short-term toxicity to fish
 - Short-term toxicity to fish.001**
 - 6.1.2 Long-term toxicity to fish
 - 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

Endpoint study record: Short-term toxicity to fish.

Detail level: all fields

Administrative Data

Purpose flag

Data waiving

Justification for data waiving

Study results

Rationale for reliability incl. deficiencies

Data source

Reference

Reference type	Author	Year
<input type="button" value="Add..."/>	<input type="button" value="Edit..."/>	<input type="button" value="Delete..."/>

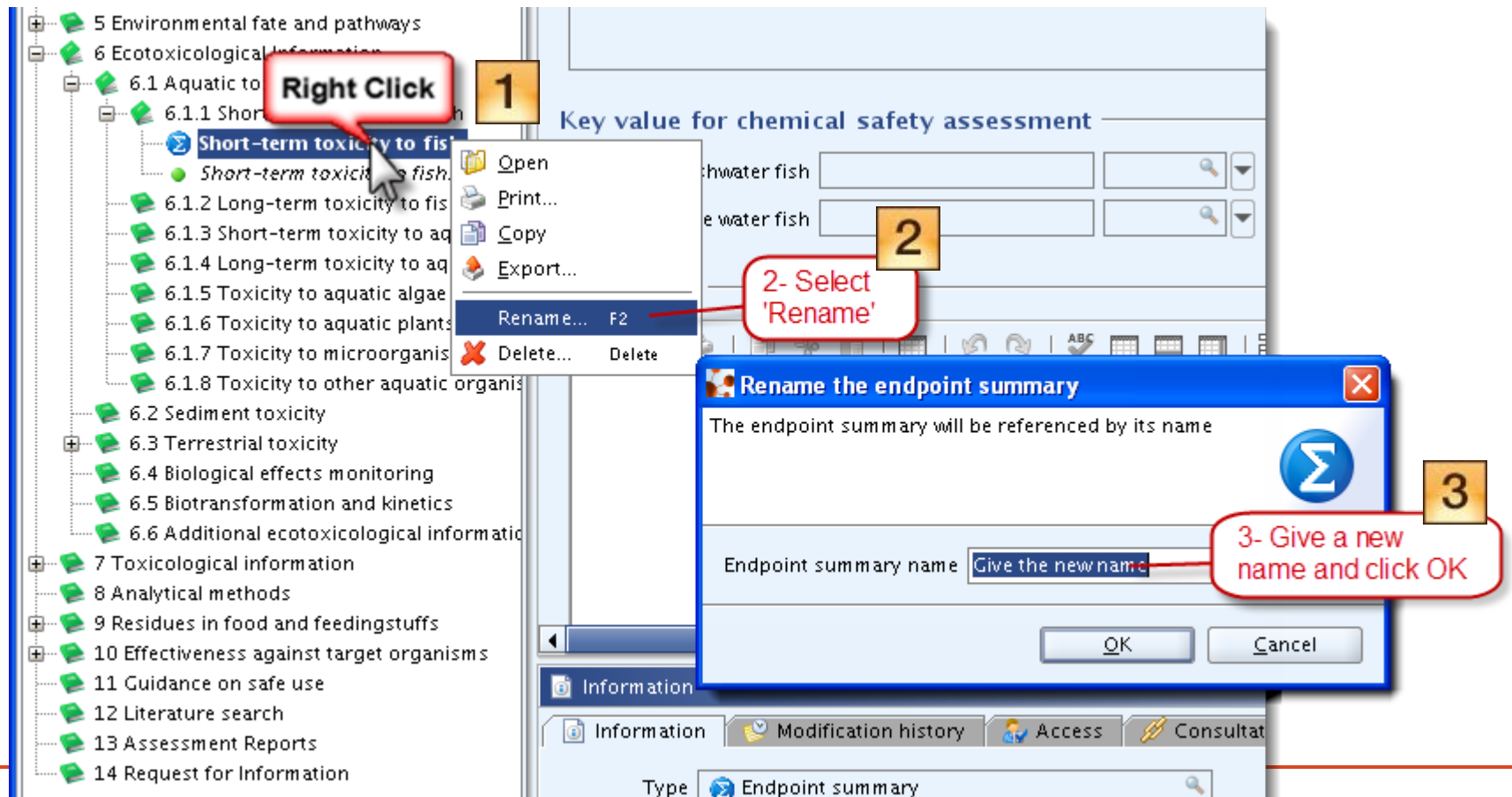
Data access

3

The newly created endpoint appears under the respective section



How to rename an endpoint



1 Right Click

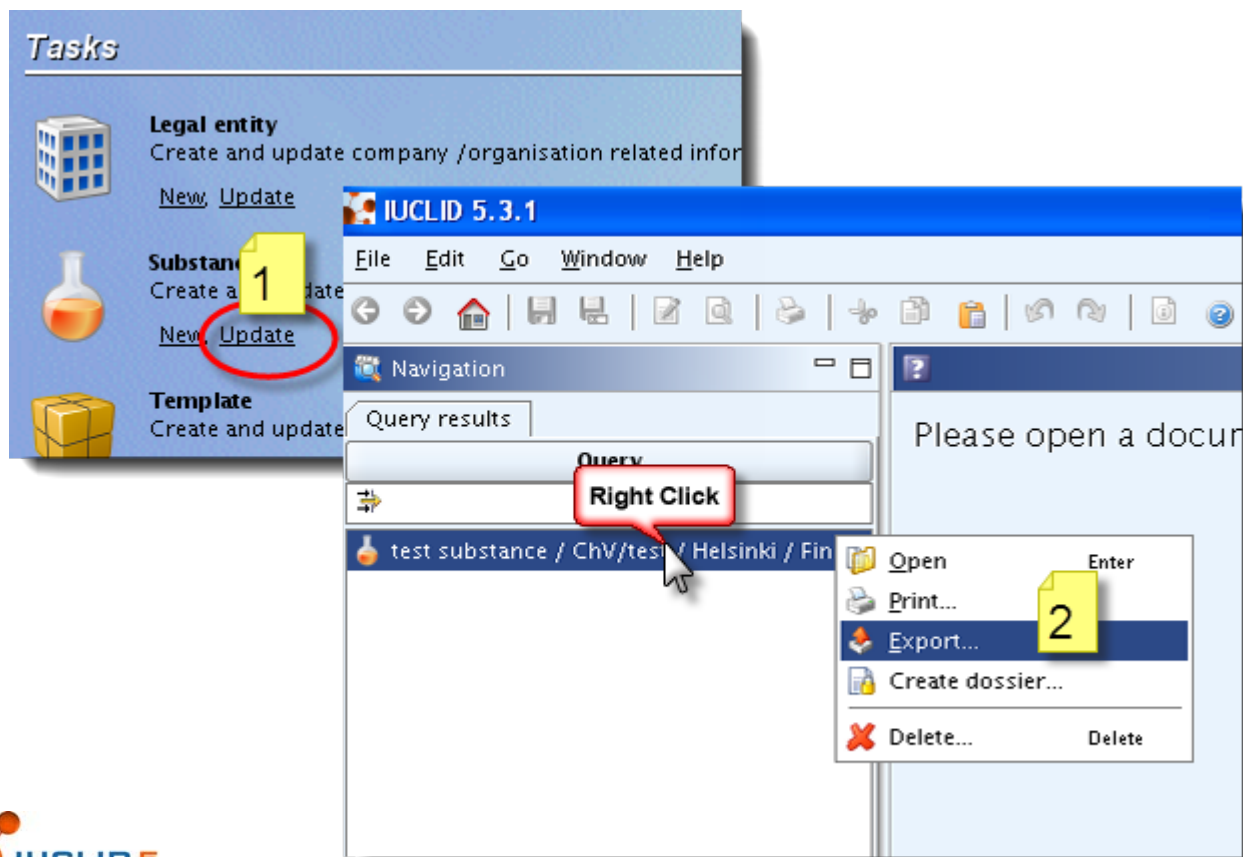
2 2- Select 'Rename'

3 3- Give a new name and click OK

Endpoint summary name

OK Cancel

How to export a substance dataset

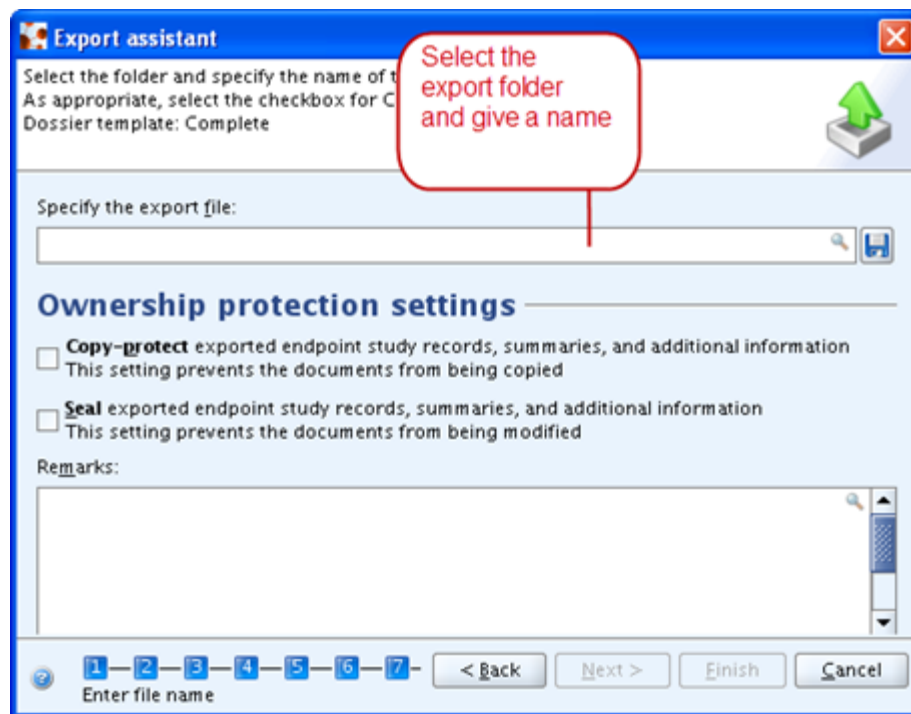


The screenshot shows the IUCLID 5.3.1 software interface. On the left, a 'Tasks' sidebar lists 'Legal entity', 'Substance', and 'Template'. The 'Substance' task is highlighted with a yellow sticky note labeled '1' and a red circle around the 'Update' link. The main window displays a 'Query results' table with one entry: 'test substance / ChV/test / Helsinki / Fin'. A red callout box labeled 'Right Click' points to this entry. A context menu is open over the entry, showing options: 'Open', 'Print...', 'Export...' (highlighted with a yellow sticky note labeled '2'), 'Create dossier...', and 'Delete...'. The 'Export...' option is also associated with the 'Enter' key.



How to export a substance dataset

- Export assistant- follow the steps
- Select 'Finish'



Assistance for the ‘Export assistant’ steps

Chapter C.7. Exporting the Substance dataset
of the IUCLID 5 End-user manual

available on the IUCLID 5 website
www.iuclid.echa.europa.eu

[IUCLID 5 End User Manuals \[top\]](#)

IUCLID 5 End User Manual

This IUCLID 5 End User Manual is designed to intended to enable any reasonably computer help desk or training. It also serves as complete possible paths through the application. This document is available in the IUCLID 5 help system, which answers your questions in a friendly way. [17MB]

[Bulgarian](#)

[Czech](#)

[Danish](#)

[German](#)

[Greek](#)

[English](#)

[Spanish](#)

[Estonian](#)

[Finnish](#)

[French](#)

[Hungarian](#)

[Italian](#)

[Lithuanian](#)

[Latvian](#)

[Maltese](#)

[Dutch](#)

[Polish](#)

[Portuguese](#)

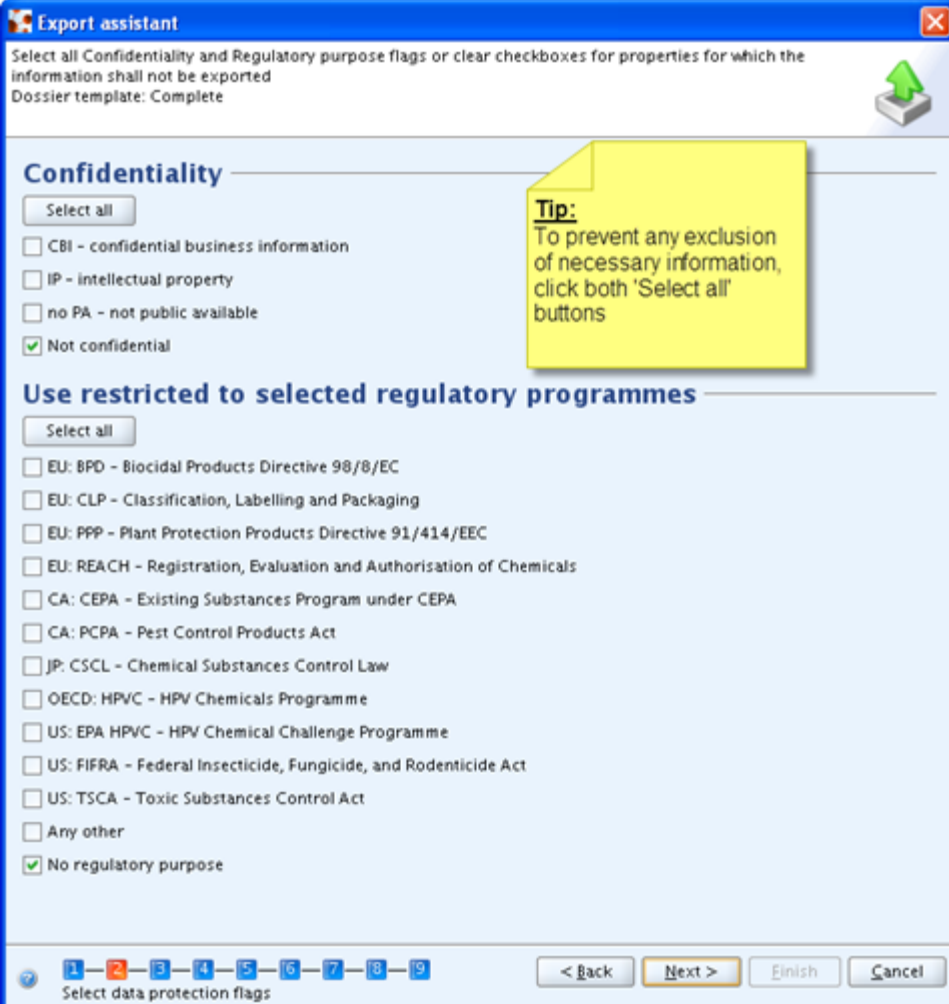
[Romanian](#)

[Slovak](#)



How to export a substance dataset

Tip for step 2
of the Export assistant



Export assistant

Select all Confidentiality and Regulatory purpose flags or clear checkboxes for properties for which the information shall not be exported
Dossier template: Complete

Confidentiality

Select all

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

Use restricted to selected regulatory programmes

Select 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

Tip:
To prevent any exclusion of necessary information, click both 'Select all' buttons

1 2 3 4 5 6 7 8 9

Select data protection flags

< Back Next > Finish Cancel



Need more explanations?

IUCLID 5 FAQs

<http://iuclid.eu/index.php?fuseaction=home.faq>



The screenshot shows the IUCLID 5 website interface. At the top, there is a header with the IUCLID 5 logo and the text "INTERNATIONAL UNIFORM CHEMICAL INFORMATION DATABASE". Below the header is a navigation menu with links for Home, IUCLID 5 Project, User Info, Download, Support, REACH, and News. Underneath the navigation menu is a secondary menu with links for Documentation, Training, Links, Get Reference substances, IUCLID format, FAQ, and ECHA Helpdesk Cor. The main content area is titled "FAQ" and has a sub-section "Import/Export". A list of three FAQ items is displayed, with the third item highlighted by a red box:

1. [Why do export file contents differ Slightly?](#)
2. [I received the error : "error java lang.OutOfMemoryError". What am I to do?](#)
3. [When exporting a Dossier, why do I sometimes get a different number of exported files?](#)



Dossier



What is a dossier

A Dossier is a
copy of selected data elements
from a substance dataset



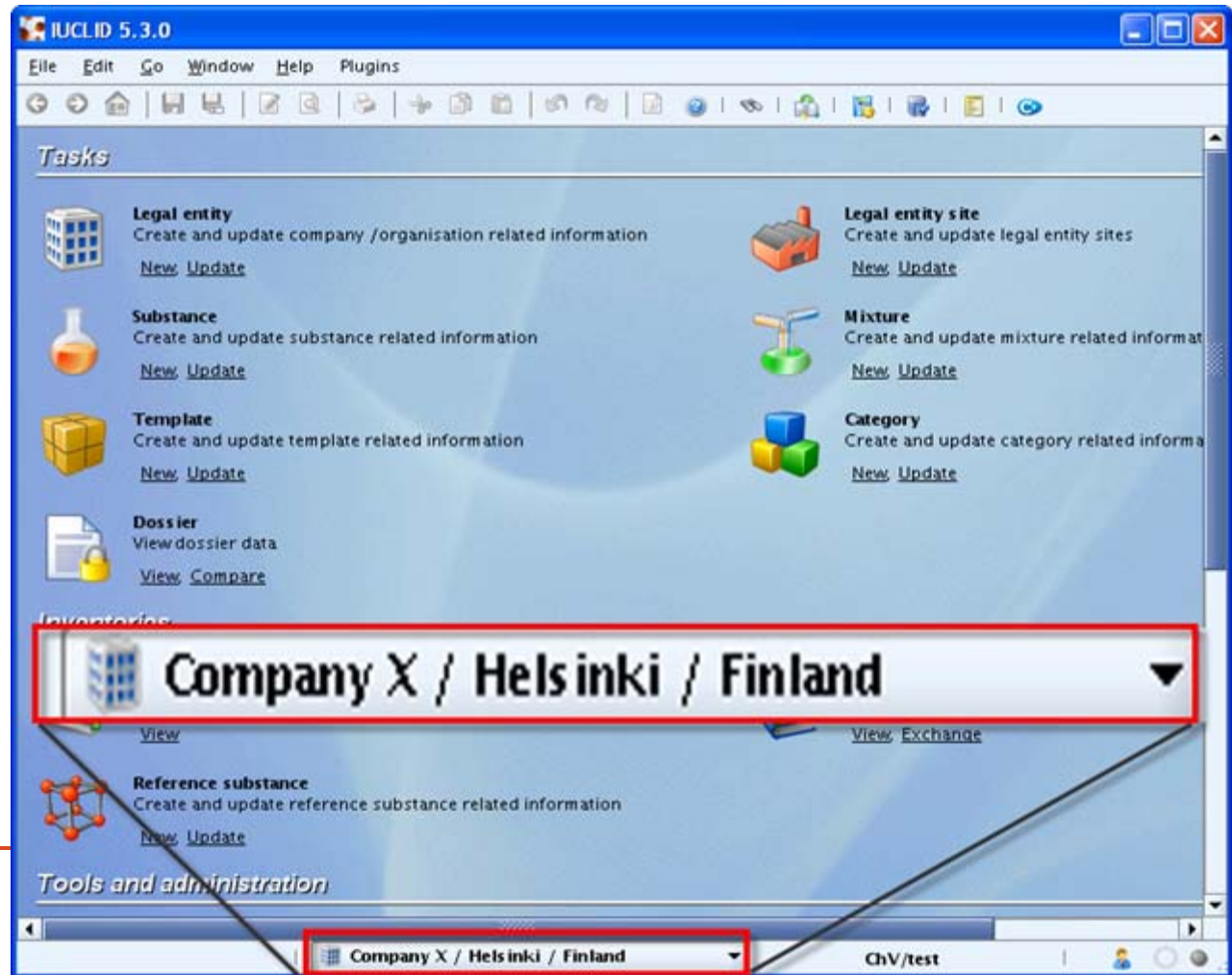
Basic functionalities on dossiers



How to create a dossier

Before you start...

Ensure that the **IUCLID Legal Entity** corresponds to the submitting **Legal Entity** in REACH-IT.



IUCLID 5.3.0

File Edit Go Window Help Plugins

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**
Create and update mixture related information
[New](#) [Update](#)
- Category**
Create and update category related information
[New](#) [Update](#)

Inventory

Company X / Helsinki / Finland

[View](#) [View](#) [Exchange](#)

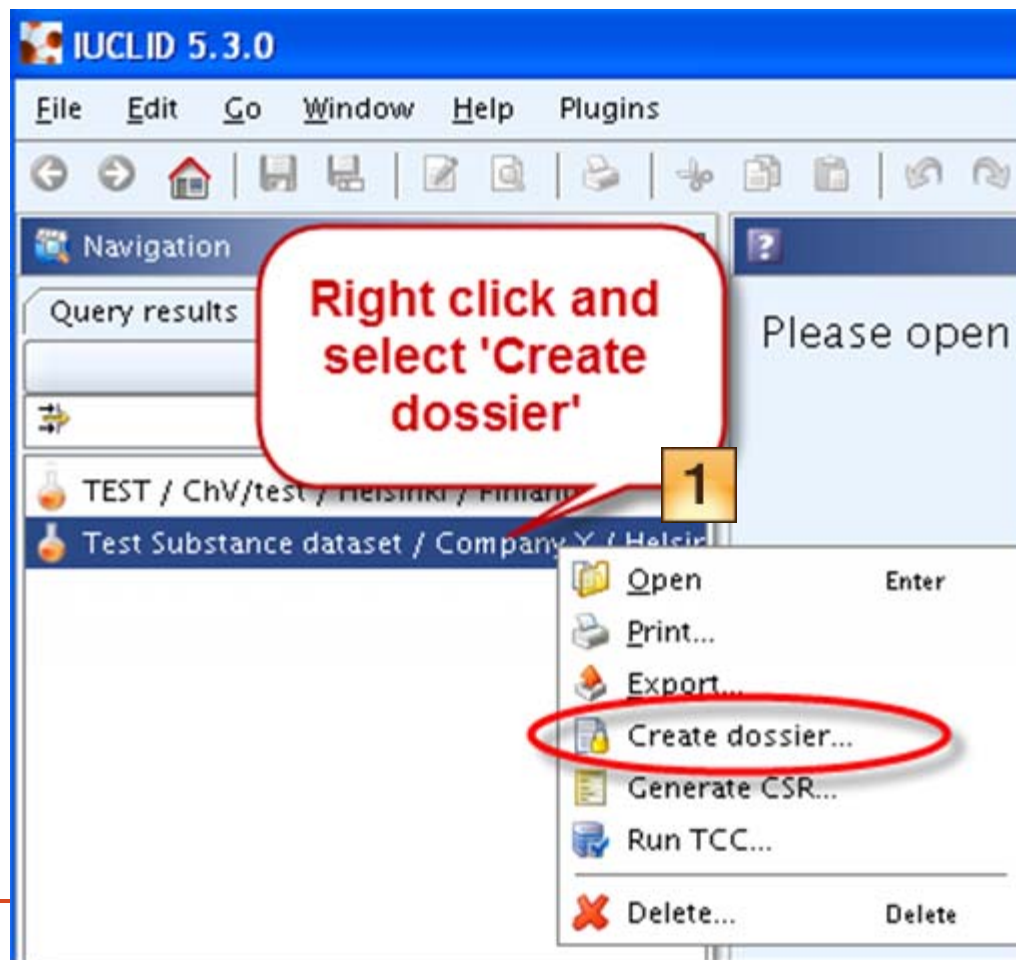
Reference substance
Create and update reference substance related information
[New](#) [Update](#)

Tools and administration

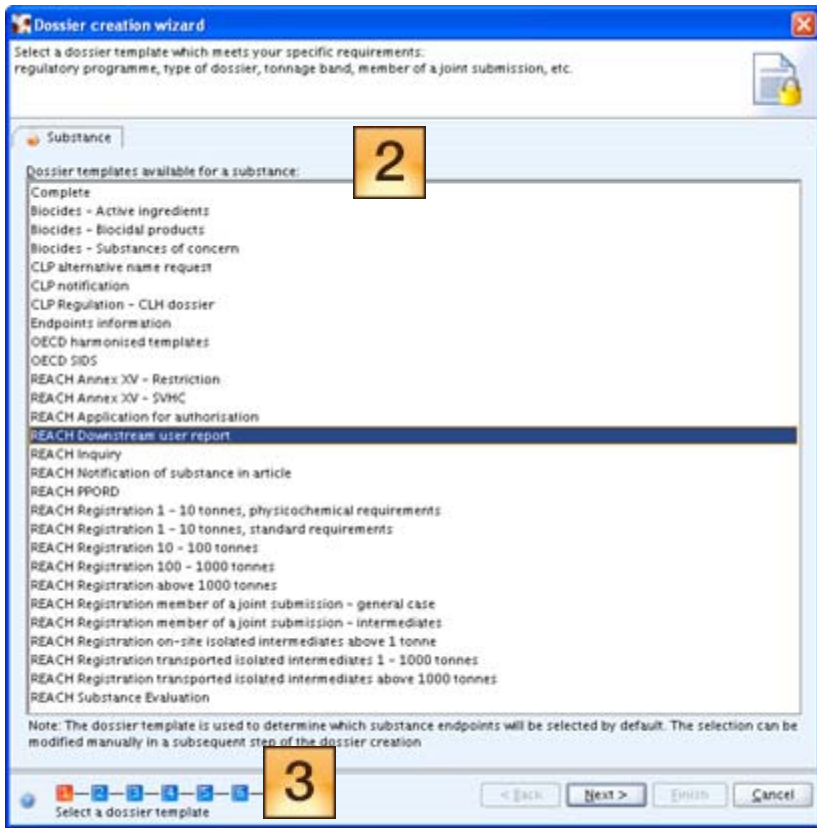
Company X / Helsinki / Finland ChV/test

How to create a dossier

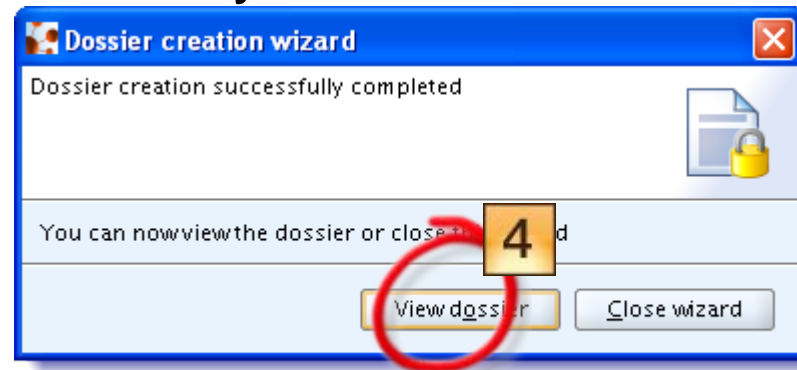
- Right click on your substance dataset
- select 'create dossier'



How to create a dossier



- Select the appropriate Dossier template
- Follow the steps
- View your dossier

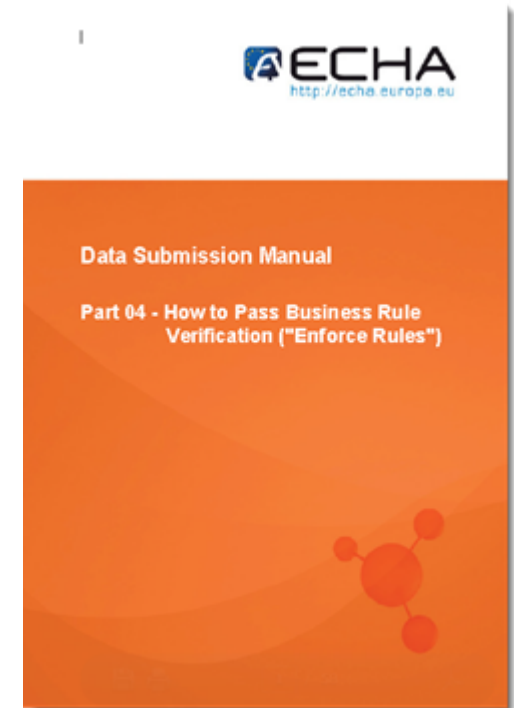


Need more help?

*REACH-IT Data Submission Manual
Part 04- How to Pass Business Rule
Verification ('Enforce Rules')*

Available at

http://echa.europa.eu/reachit/dsm_en.asp



Dossier updates

Reason for updating

- Further to a request/decision from regulatory body
- Spontaneous update

Tip:

Useful for the
step 6 of the
Dossier
creation wizard



Requested update- why?

- Technical completeness check failures
- During the evaluation process
- During the assessment of confidentiality claims



Spontaneous update- why?

- Change of tonnage band
 - Change in classification and labelling
 - New or update of CSR or guidance on safe use
 - New identified uses
 - Change in composition of the substance
- etc...



Dossier updates- requested update

- Give the number of the last successful submission
- Select the reason for updating -requested update
- Provide the reference number of the communication letter

Specific submissions

The submission is an update

Last submission number

Reason for updating

Further to a request/decision from regulatory body

Spontaneous update

Number

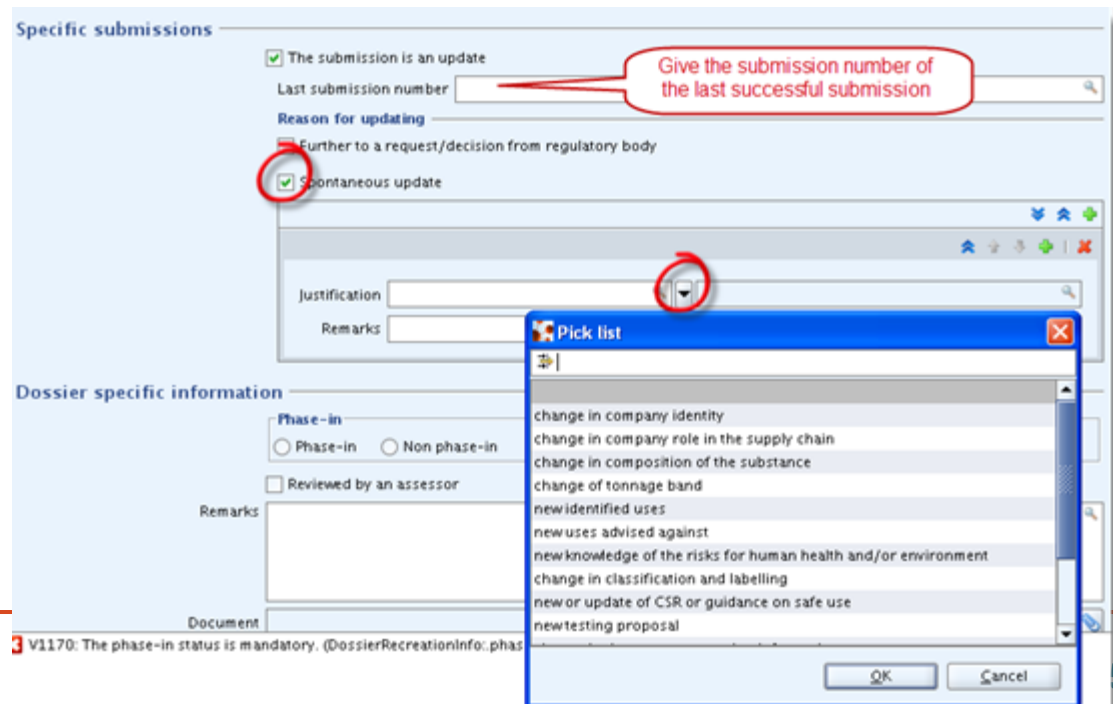
Remarks

Give the submission number of the last successful submission

Provide the communication letter reference

Dossier updates- spontaneous update

- Give the number of the last successful submission
- Select the reason for updating- spontaneous
- Provide the justification



Specific submissions

The submission is an update

Last submission number

Reason for updating

Further to a request/decision from regulatory body

Spontaneous update

Justification

Remarks

Dossier specific information

Phase-in

Phase-in Non phase-in

Reviewed by an assessor

Remarks

Document

Pick list

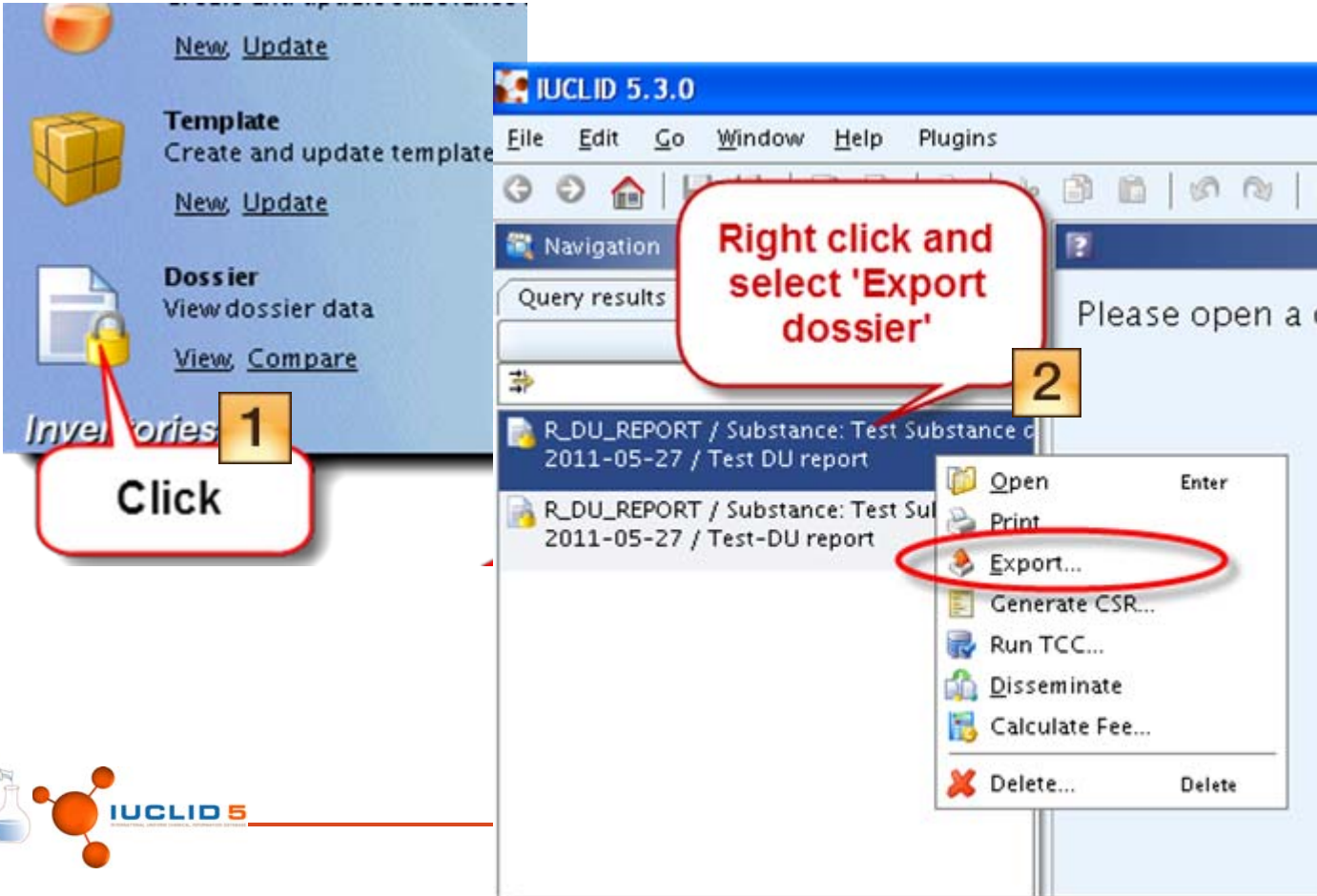
- change in company identity
- change in company role in the supply chain
- change in composition of the substance
- change of tonnage band
- new identified uses
- new uses advised against
- new knowledge of the risks for human health and/or environment
- change in classification and labelling
- new or update of CSR or guidance on safe use
- new testing proposal

V1170: The phase-in status is mandatory. (DossierRecreationInfo:phas

OK Cancel



How to export a dossier



The screenshot shows the IUCLID 5.3.0 interface. On the left, a sidebar contains several menu items: 'New, Update' (with an orange sphere icon), 'Template' (with a yellow cube icon), and 'Dossier' (with a document icon and a yellow padlock). A red arrow points from the 'Dossier' icon to a yellow box with the number '1' and the word 'Click'. The main window displays a list of reports, including 'R_DU_REPORT / Substance: Test Substance of 2011-05-27 / Test DU report'. A red speech bubble with the text 'Right click and select 'Export dossier'' points to a yellow box with the number '2'. A context menu is open over the selected report, with the 'Export...' option circled in red.

1
Click

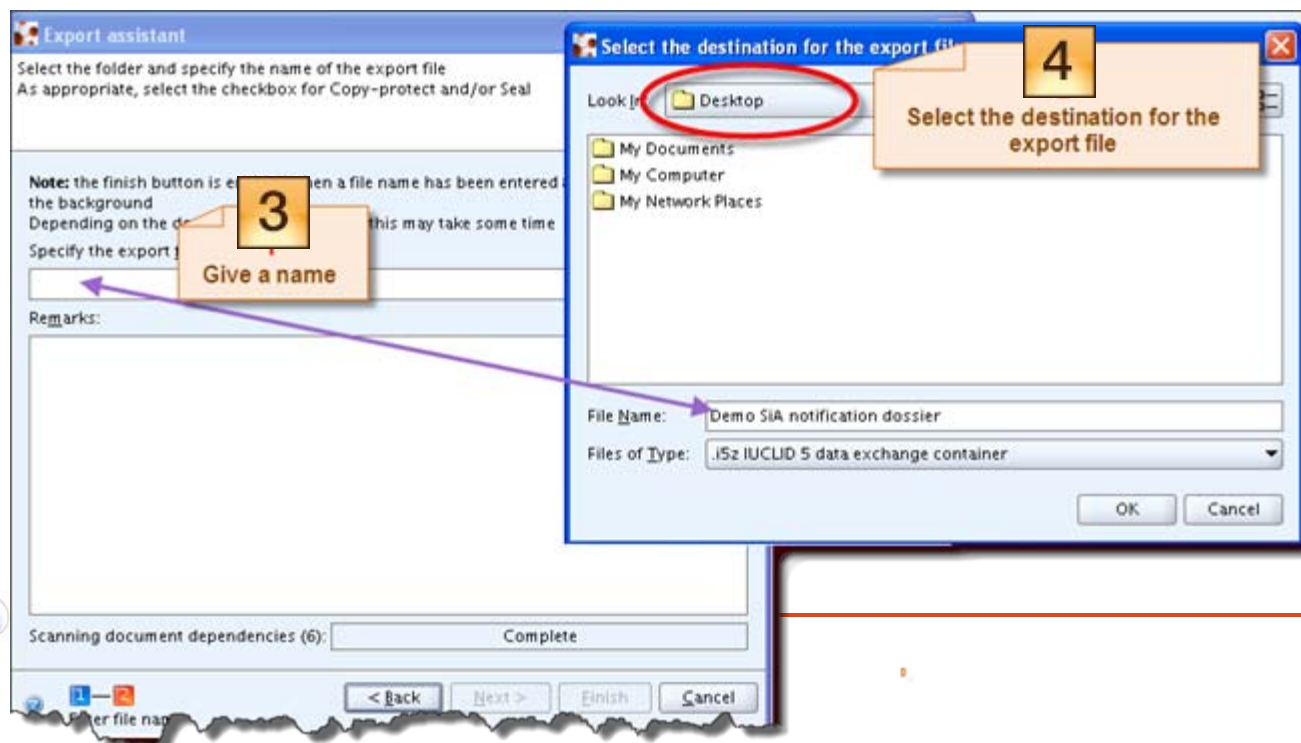
2
Right click and select 'Export dossier'

Export...

How to export a dossier

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

Tip:
Save it on
your desktop!

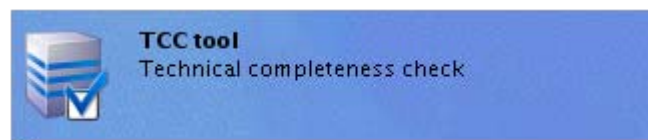


Technical completeness check (TCC) plug-in



The Technical Completeness Check (TCC) plug-in:

- Checks the completeness of substance datasets and dossiers
 - for the purpose of registrations and PPORD notifications under the REACH regulation
- Covers part of the business rules check
 - for registration dossiers, downstream user reports, PPORD, substance in articles and inquiry notifications under the REACH Regulation, and CLP notifications under the CLP Regulation



Note: It validates only REACH regulation dossiers for their completeness

The Technical Completeness Check (TCC) plug-in:

NEW!

Version 5.3.1 of the TCC plug-in now includes the possibility to check substance datasets and dossiers for inquiry notifications using a Substance Identity (SID) check

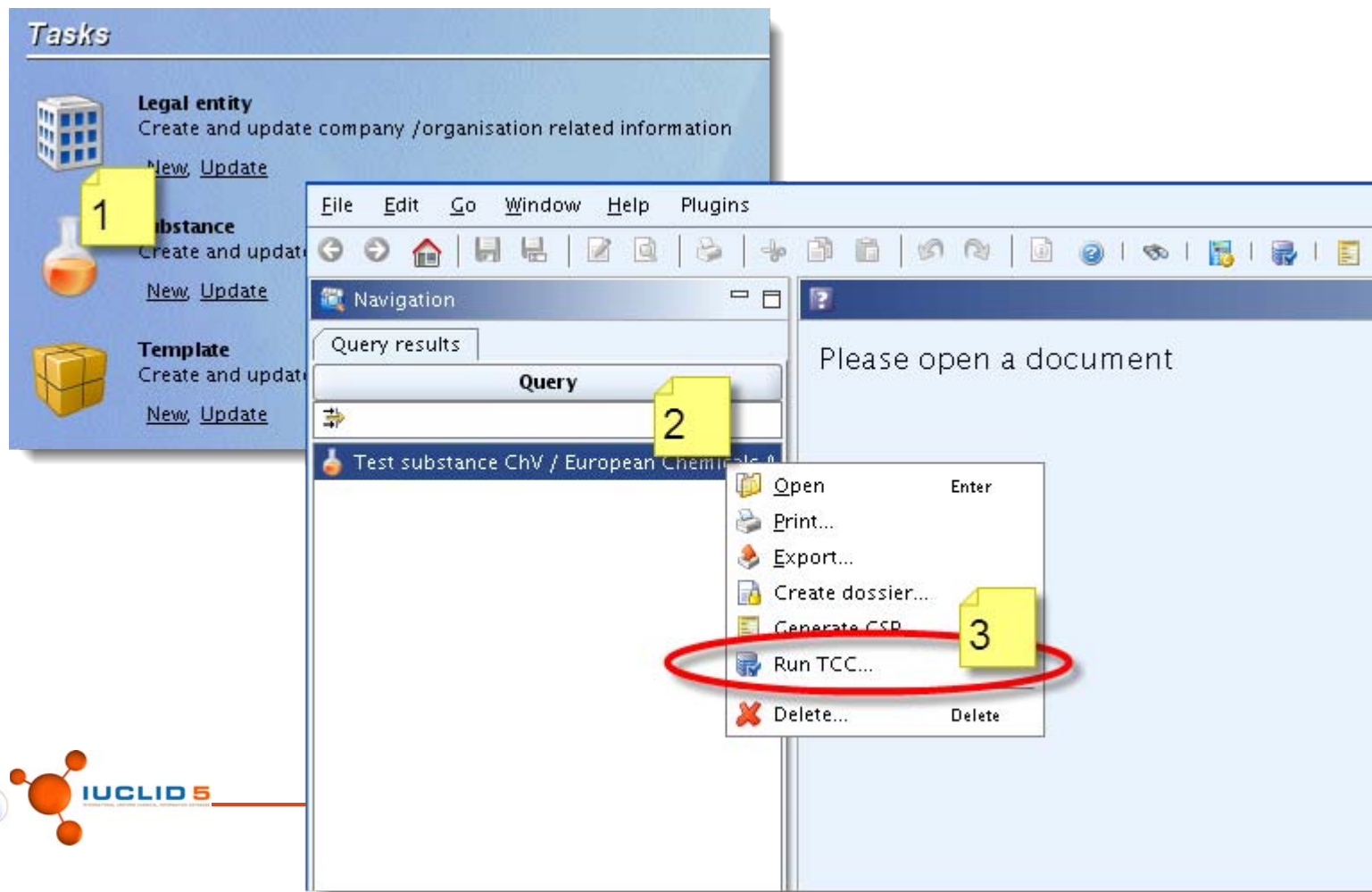


Note: It validates only REACH regulation dossiers for their completeness

Basic functionalities of the TCC plug-in on Substance datasets



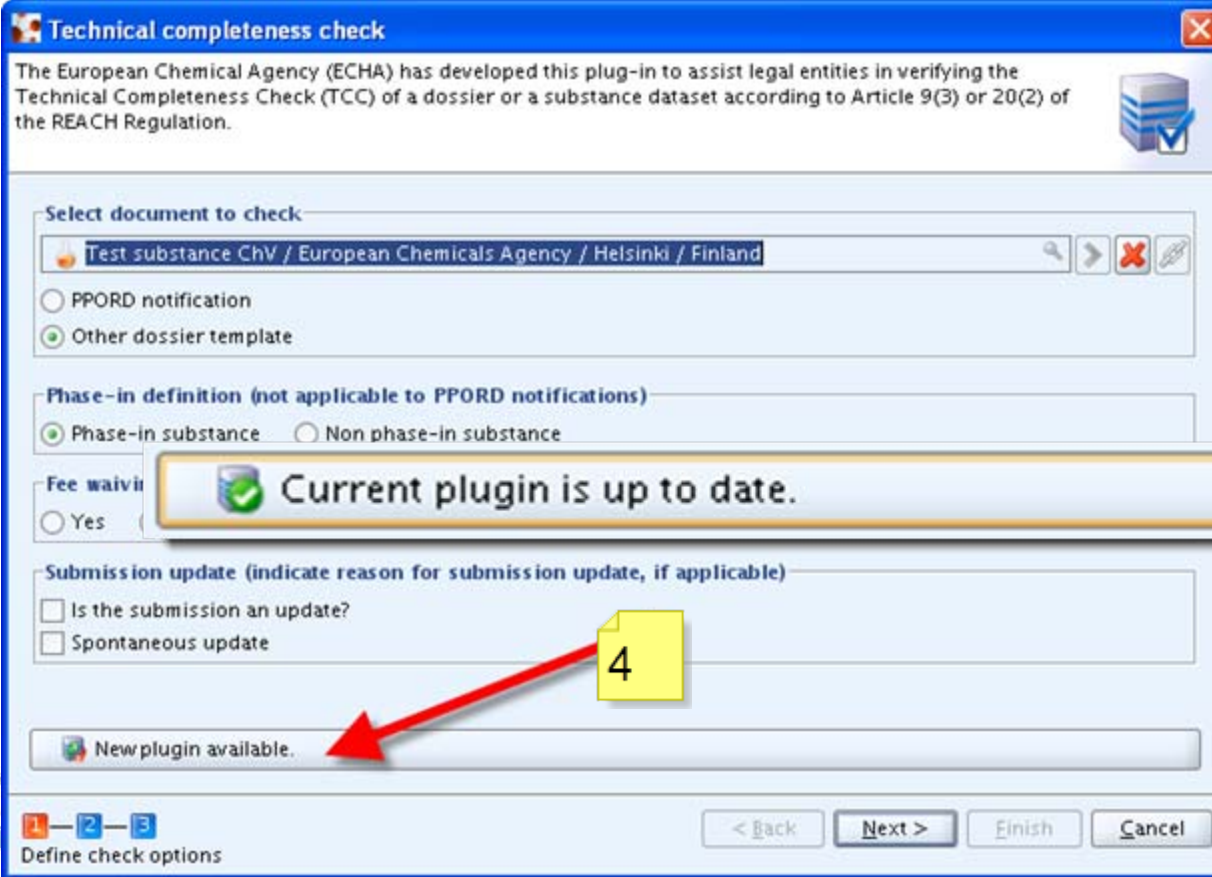
Run the TCC on a Substance dataset



The screenshot displays the IUCLID 5 software interface. On the left, the 'Tasks' panel lists three main categories: 'Legal entity', 'Substance', and 'Template'. The 'Substance' category is highlighted with a yellow sticky note labeled '1'. In the center, a 'Query' window is open, showing a search bar with a yellow sticky note labeled '2'. A context menu is open over the search bar, with the 'Run TCC...' option circled in red and a yellow sticky note labeled '3' next to it. The menu also includes options like 'Open', 'Print...', 'Export...', 'Create dossier...', 'Generate CSP', and 'Delete...'. The background shows a 'Please open a document' dialog box.



Run the TCC on a Substance dataset



Technical completeness check

The European Chemical Agency (ECHA) has developed this plug-in to assist legal entities in verifying the Technical Completeness Check (TCC) of a dossier or a substance dataset according to Article 9(3) or 20(2) of the REACH Regulation.

Select document to check

Test substance ChV / European Chemicals Agency / Helsinki / Finland

PPORD notification

Other dossier template

Phase-in definition (not applicable to PPORD notifications)

Phase-in substance Non phase-in substance

Fee waiver

Yes No

Submission update (indicate reason for submission update, if applicable)

Is the submission an update?

Spontaneous update

New plugin available.

1 2 3 Define check options

< Back Next > Finish Cancel

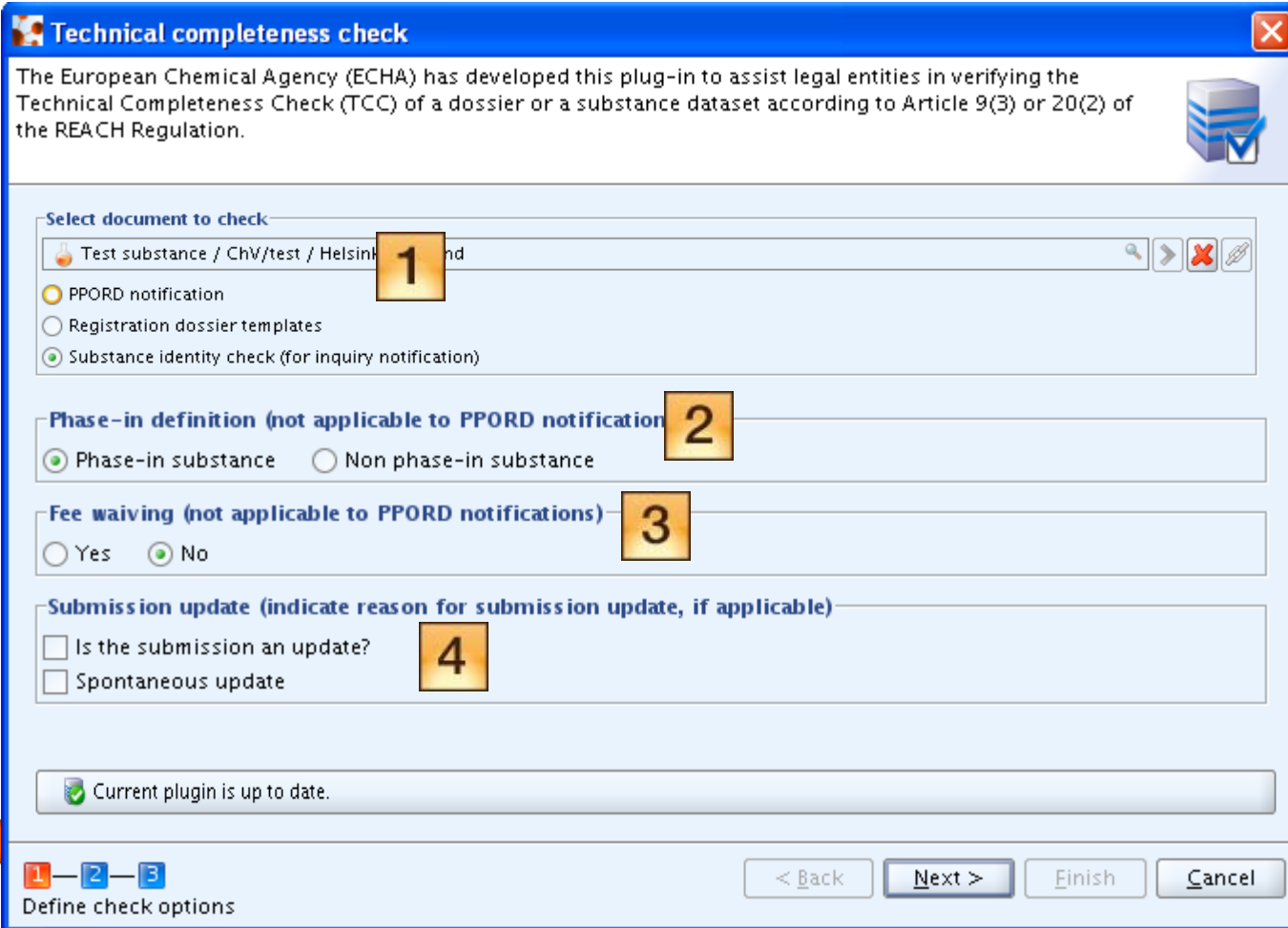


Tip:

You must install the new version of the plug-in manually.
It is not done automatically



Run the TCC on a Substance dataset



Technical completeness check

The European Chemical Agency (ECHA) has developed this plug-in to assist legal entities in verifying the Technical Completeness Check (TCC) of a dossier or a substance dataset according to Article 9(3) or 20(2) of the REACH Regulation.

Select document to check

Test substance / ChV/test / Helsinki **1**

PPORD notification
 Registration dossier templates
 Substance identity check (for inquiry notification)

Phase-in definition (not applicable to PPORD notification) **2**

Phase-in substance Non phase-in substance

Fee waiving (not applicable to PPORD notifications) **3**

Yes No

Submission update (indicate reason for submission update, if applicable)

Is the submission an update? **4**
 Spontaneous update

Current plugin is up to date.

1 — **2** — **3**
Define check options

< Back Next > Finish Cancel

Run the TCC on a Substance dataset

Technical completeness check

The European Chemical Agency (ECHA) has developed this plug-in to assist legal entities in verifying the Technical Completeness Check (TCC) of a dossier or a substance dataset according to Article 9(3) or 20(2) of the REACH Regulation.

5 **Joint Submission**

No Yes

6 **Role in the Joint submission**

Member of a joint submission

Lead registrant of a joint submission

The lead registrant should select here below the dossier type that refers to the joint submission dossier.

In general only one dossier type must be selected, either in the picklist "Registration dossier" or in the picklist "Intermediates". In exceptional case where the registrant would like to submit a combined dossier which would cover a standard registration as well as an intermediate use, then an item in both picklists must be selected.

Registration dossier: 10 - 100 tonnes

Intermediates: not applicable

1 - 2 - 3
Define dossier options

< Back Next > Finish Cancel



Run the TCC on a Substance dataset

Technical completeness check

The European Chemicals Agency (ECHA) has developed this plug-in to assist legal entities in verifying the Technical Completeness Check (TCC) of a dossier or a substance dataset according to Article 9(3) or 20(2) of the REACH Regulation.

Joint Submission

No Yes

Role in the joint submission **6**

Member of a joint submission

Tonnage band of the joint submission: Registration dossier above 1000 tonnes

Tonnage band of the member

Tonnage band (standard registration): Between 100 to 1000 tonnes/year

On-site isolated intermediate tonnage band:

Transported isolated intermediate tonnage band:

Provided by lead

Guidance on safe use Chemical Safety Report

Lead registrant of a joint submission

In general only one dossier type must be selected, either in the picklist "Registration dossier" or in the picklist "Intermediate". In exceptional case where the registrant would like to submit a combined dossier which would cover a standard registration as well as an intermediate use, then an item in both picklists must be selected.

Registration dossier: not applicable

Intermediates: not applicable

7

1 — 2 — 3

Define dossier options

< Back Next > Finish Cancel



Run the TCC on a Substance dataset

Technical completeness check

The European Chemical Agency (ECHA) has developed this plug-in to assist legal entities in verifying the Technical Completeness Check (TCC) of a dossier or a substance dataset according to Article 9(3) or 20(2) of the REACH Regulation.

Filter: Show all with type failure, warning

Section number	Section name	Endpoint name	Failure description	Type
Section 1.1			Section 1.1 is invalid or missing	TCC failure
Section 1.1	Identification		At least one "role in the supply chain" must be selected. NB: If you are a manufacturer, you must also fill in Section 3.1 "Technological process" and 3.3 "Sites" (including the address of each site).	TCC failure
Section 1.1	Identification		'mono constituent substance', 'multi constituent substance' or 'UVCB' should be selected in the field 'Composition' under 'Type of substance'.	TCC failure
Section 1.1	Identification		A reference substance must be provided.	TCC failure
Section 1.1	Identification		Reference substance information is not complete. Either IUPAC name or EC number or CAS number and CAS name must be provided in the corresponding IUCLID 5 fields. It is not enough to provide required information only in the reference substance name.	TCC failure
Section 1.1	Identification		The reference substance must be updated. If you indicate "mono constituent substance" in section 1.1 under "Type	TCC failure

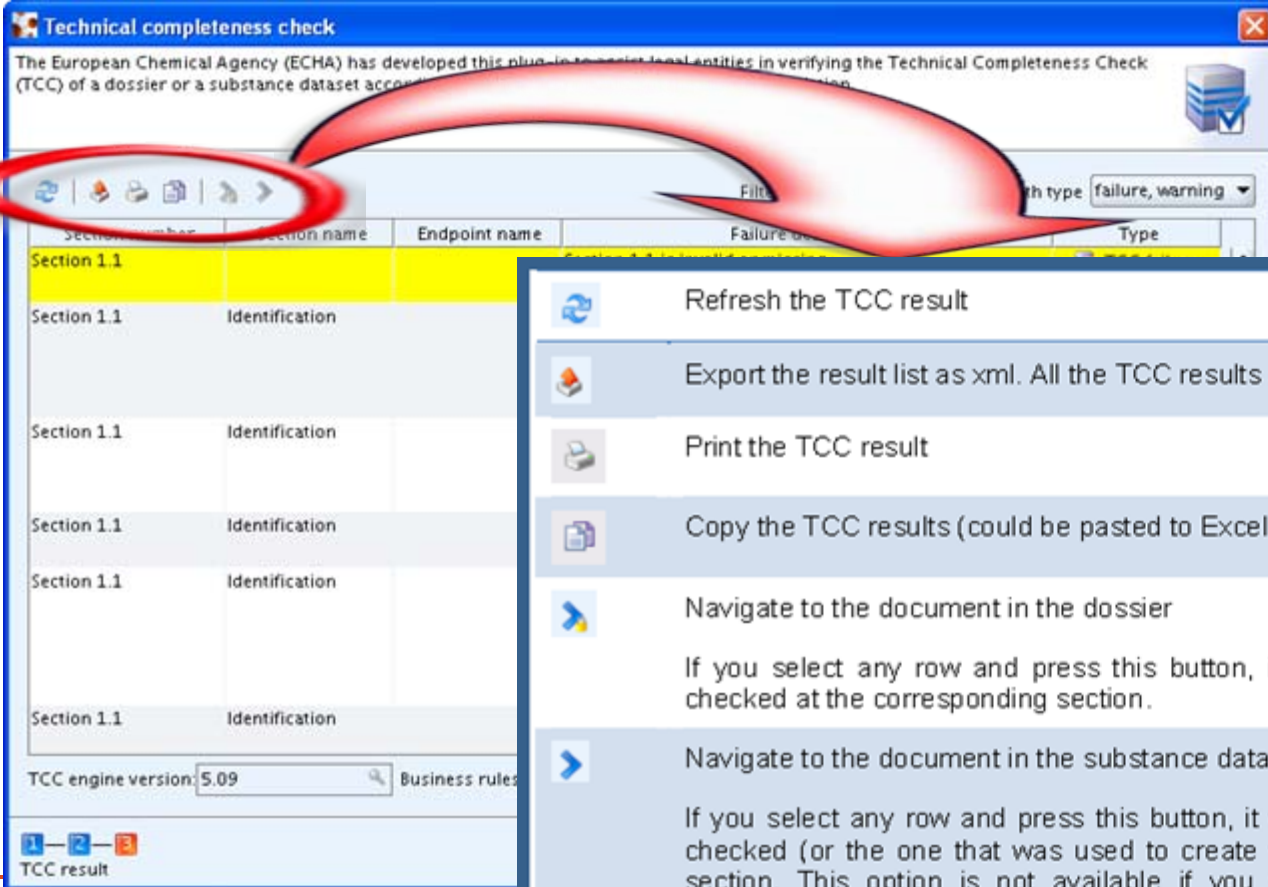
TCC engine version: 5.09 Business rules version: 2.1.1 Completeness rules version: 2.1.1.0

1 2 3
TCC result







< Back Next > Finish Cancel



Results list interface



The screenshot shows the 'Technical completeness check' window. At the top, there is a toolbar with several icons: a refresh icon, an export icon, a print icon, a copy icon, and a navigation icon. A red circle highlights these icons, and a red arrow points from the circle to a callout box. The main area contains a table with columns for 'Section number', 'Section name', 'Endpoint name', 'Failure description', and 'Type'. The table lists several 'Section 1.1' entries, all with 'Identification' as the section name. At the bottom, there is a 'TCC engine version' field showing '5.09' and a 'Business rules' field.

-  Refresh the TCC result
-  Export the result list as xml. All the TCC results are exported in a XML file.
-  Print the TCC result
-  Copy the TCC results (could be pasted to Excel, Word...)
-  Navigate to the document in the dossier
If you select any row and press this button, it will open the dossier which was checked at the corresponding section.
-  Navigate to the document in the substance dataset
If you select any row and press this button, it will open the substance which was checked (or the one that was used to create your dossier) at the corresponding section. This option is not available if you were checking a dossier but the substance dataset that was used to generate that dossier is not in your IUCLID database.

What do the results mean?

Technical completeness check

The European Chemical Agency (ECHA) has developed this plug-in to assist legal entities in verifying the Technical Completeness Check (TCC) of a dossier or a substance dataset according to Article 9(3) or 20(2) of the REACH Regulation.

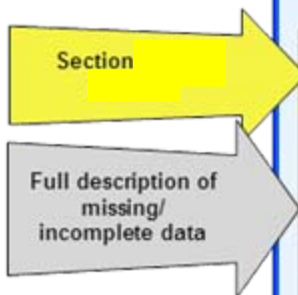
Filter: with type

Section number	Section name	Endpoint name	Failure description	Type
Section 3.4			Failure in Business Rule BR152	BR failure
Section 3.4	Form in the supply chain, (1)		Section 3.4 of your submitted dossier is not complete. At least one block must be created under 'Substance in article' and the corresponding tickbox must be ticked. For each block entered the 'Description of article' text field must be filled in.	BR failure

TCC engine version: 5.09 Business rules version: 2.1.4 Completeness rules version: 2.1.1.0

< Back Next > Finish Cancel

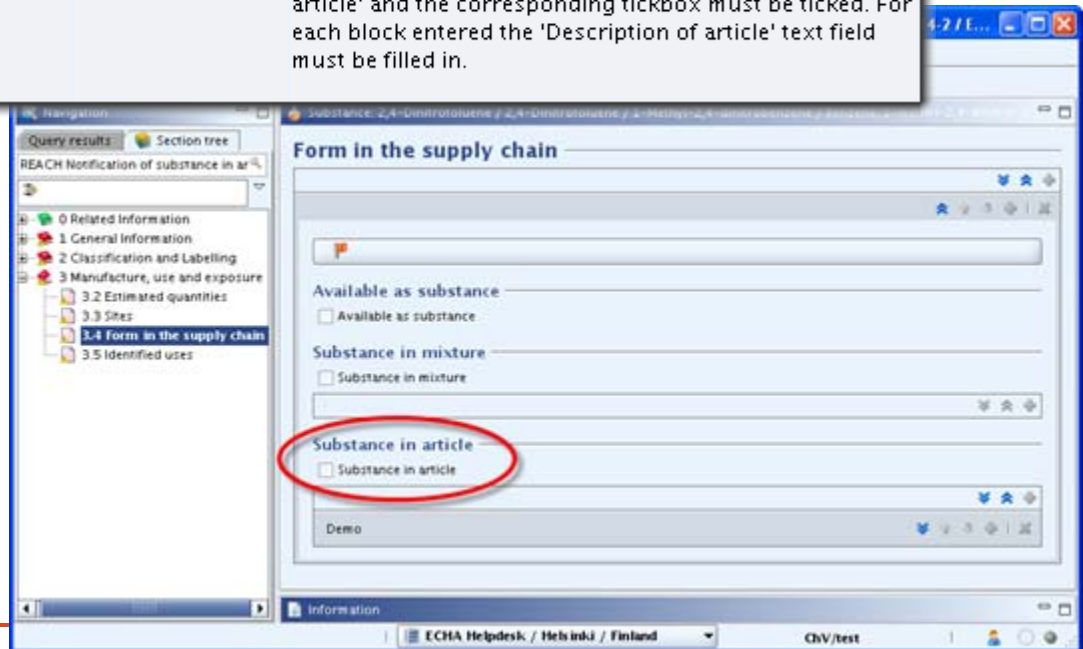
TCC result



What do the results mean?

Example

Section 3.4		Failure in Business Rule BR152
Section 3.4	Form in the supply chain, (1)	Section 3.4 of your submitted dossier is not complete. At least one block must be created under 'Substance in article' and the corresponding tickbox must be ticked. For each block entered the 'Description of article' text field must be filled in.



The screenshot shows the 'Form in the supply chain' section of a REACH notification. The left sidebar shows a navigation tree with '3.4 Form in the supply chain' selected. The main content area contains several sections with checkboxes:

- Available as substance
 - Available as substance
- Substance in mixture
 - Substance in mixture
- Substance in article** (circled in red)
 - Substance in article

At the bottom of the form, there is a 'Demo' button. The status bar at the bottom indicates 'ECHA Helpdesk / Helsinki / Finland' and 'ChV/test'.



Types of messages

BR warnings

A warning message appears for some business rules that cannot be completely simulated outside REACH-IT. Therefore, the plug-in just gives a warning message, meaning that your dossier could fail the business rules in the submission process, but it is not totally certain since the concerned business rule was too complex to be fully implemented in the TCC plugin. These messages appear flagged with the icon.



Types of messages

BR failures 

These messages are associated with business rules in REACH-IT which could be correctly simulated in the TCC plugin. If you submit a dossier without correcting the issue mentioned in the message, your dossier will fail the business rules check during the submission process. These messages appear flagged with the icon above.



Types of messages

TCC warnings

A TCC warning does not mean that your dossier will fail the TCC. It simply informs you of some information that should normally be in your registration dossier. However you are advised to try to correct the issue that raised the warning message, since it could have implications for the compliance of your dossier. These messages are flagged with the icon above.



Types of messages

TCC failures

These messages correspond to the Technical Completeness Check. If you do not correct the issue mentioned in one of these messages, your dossier will fail the TCC. These messages are flagged with the icon above.



Types of messages - summary

BR warnings

BR failures

TCC warnings

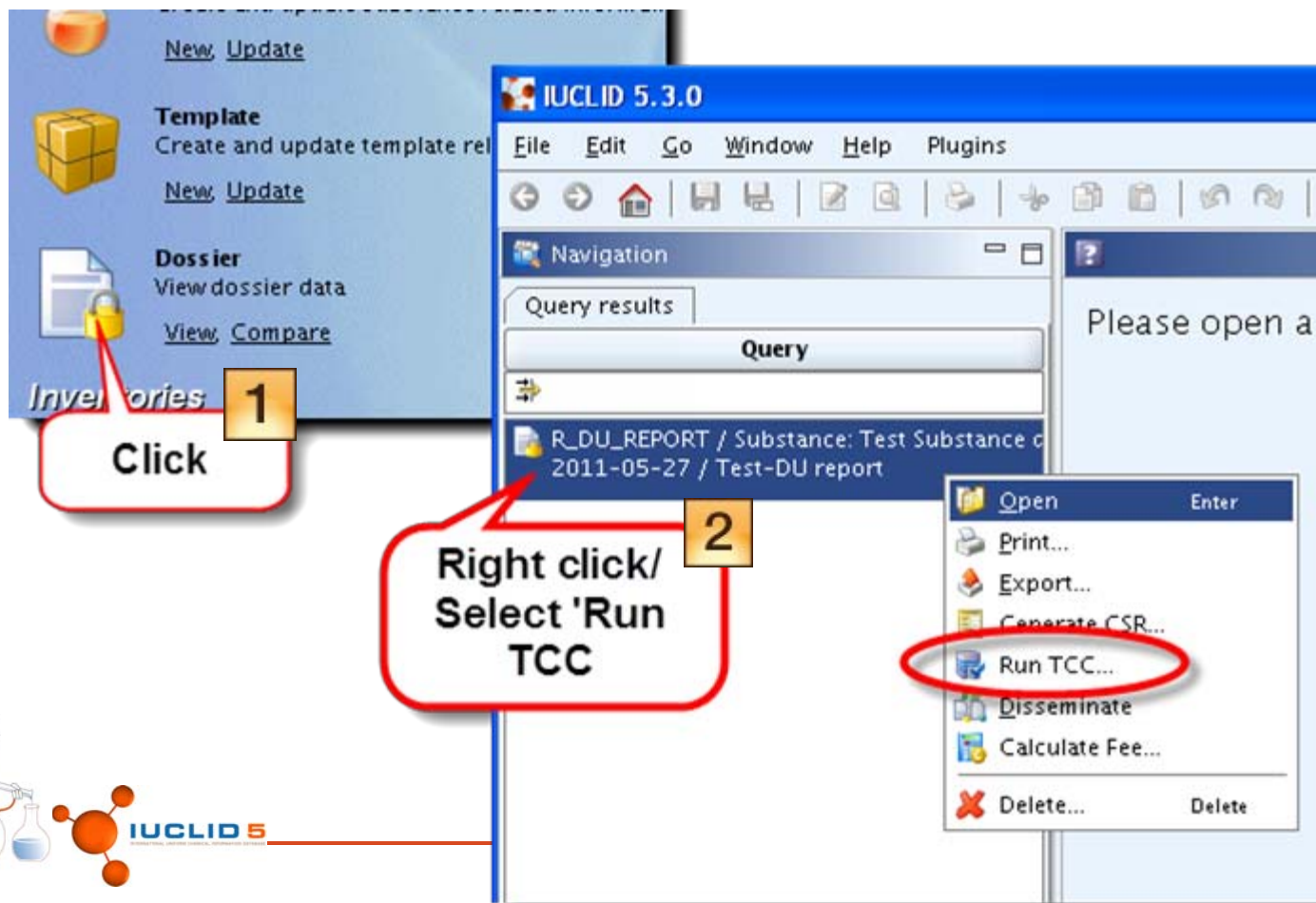
TCC failures



Basic functionalities of the TCC plug-in on dossiers



How to run the TCC on a dossier



The screenshot shows the IUCLID 5.3.0 interface. On the left, the 'Inventories' section is highlighted with a red box and a yellow callout box containing the number '1'. Below this, a red box contains the text 'Click'. In the center, the 'Navigation' pane shows a list of items, with 'R_DU_REPORT / Substance: Test Substance of 2011-05-27 / Test-DU report' selected. A red box with a yellow callout box containing the number '2' points to this item, with the text 'Right click/ Select 'Run TCC''. A context menu is open over this item, with the 'Run TCC...' option circled in red.

1
Click

2
Right click/
Select 'Run
TCC

- Open Enter
- Print...
- Export...
- Generate CSR...
- Run TCC...**
- Disseminate
- Calculate Fee...
- Delete... Delete



What to do if there are failures?



Technical completeness check

The European Chemical Agency (ECHA) has developed this plug-in to assist legal entities in verifying the Technical Completeness (TCC) of a dossier or a substance dataset according to Article 9(3) or 20(2) of the REACH Regulation.

Filter: with type

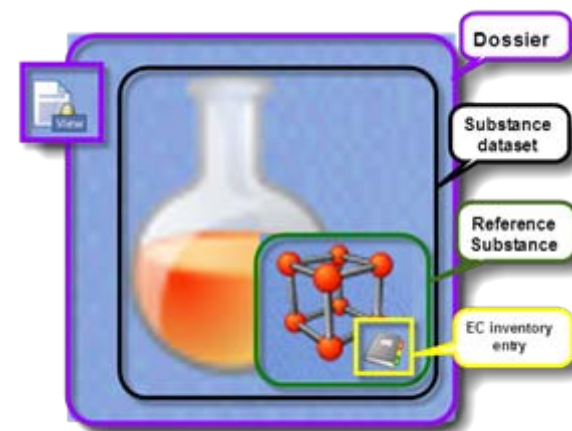
Section number	Section name	Endpoint name	Failure description	Type
Section 1.3			Failure in Business Rule BR136	BR failure
Section 1.3	Identifiers		The REACH registration number you have provided in Section 1.3 is not a valid registration number.	BR failure
Section 1.7			Failure in Business Rule BR151	BR failure
Section 1.7	Suppliers, (1)		The supplier information provided in section 1.7 of your	BR failure

TCC engine version: Business rules version: Completeness rules version:

TCC result: 1 2 3

What to do if there are failures?

1. Correct the missing/ incomplete data in the **Substance Dataset**
2. Re-create a dossier **AGAIN**



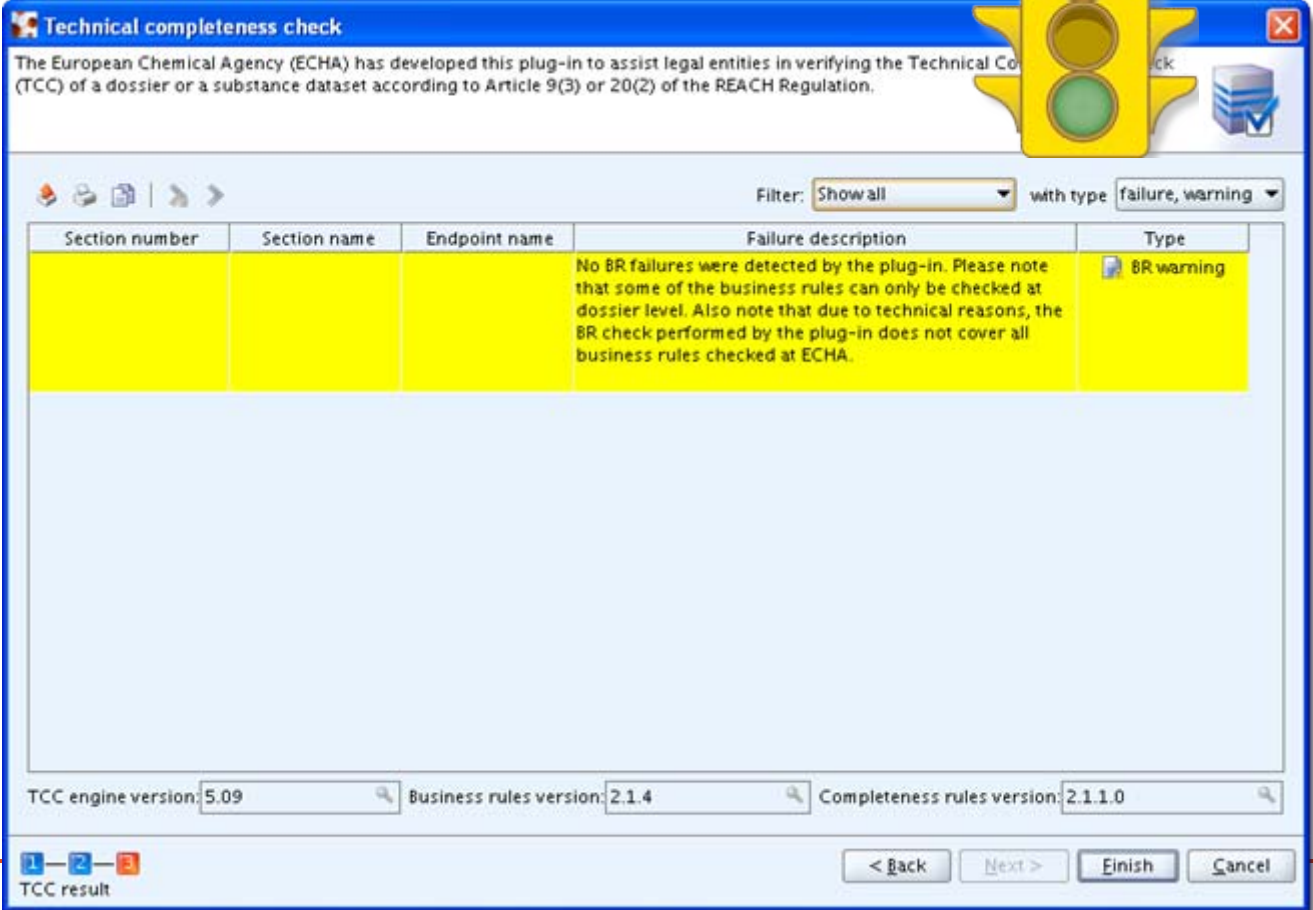
**Dossier
mode:
Read-only**


a Dossier can NOT be modified

What to do if there are no failures



- Export your dossier
- Submit it to ECHA



Section number	Section name	Endpoint name	Failure description	Type
			No BR failures were detected by the plug-in. Please note that some of the business rules can only be checked at dossier level. Also note that due to technical reasons, the BR check performed by the plug-in does not cover all business rules checked at ECHA.	 BR warning



Summary



What did you learn today

- IUCLID 5 User interface and basic functionalities
- The various elements included in a dossier- Anatomy
- Substance dataset (root element, endpoints)
- Basic functionalities in the reference substance(s), substance dataset(s) and in dossier(s)
- Use and understanding of Technical completeness check (TCC) plug-in



Further information

- If you need assistance on how to download and install IUCLID 5 (stand-alone application), see our video '*IUCLID 5 standalone installation*' on the IUCLID 5 website, under section 'training'
- If you need assistance on your first steps with IUCLID 5, see our presentation '*Necessary preparation before you start*' available on the ECHA website



Thank you for your attention!

