

Overview on IUCLID and dossier creation

19 October 2012
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Content

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

What is IUCLID 5 and where to find it



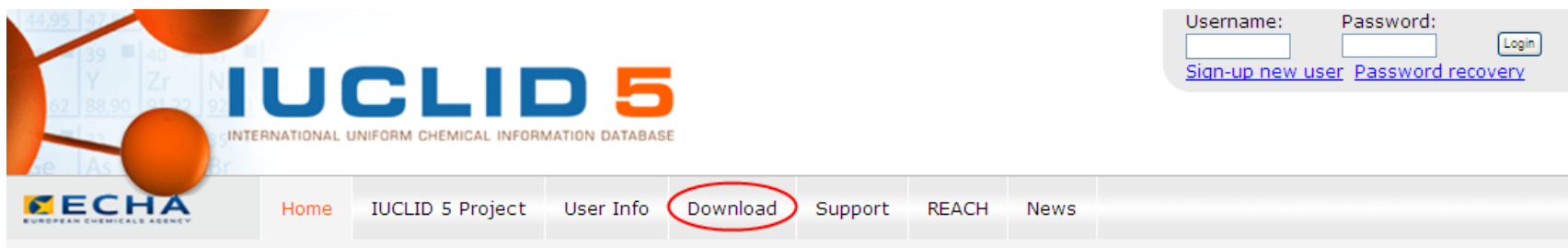
What is IUCLID 5

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

INTERNATIONAL UNIFORM CHEMICAL INFORMATION DATABASE

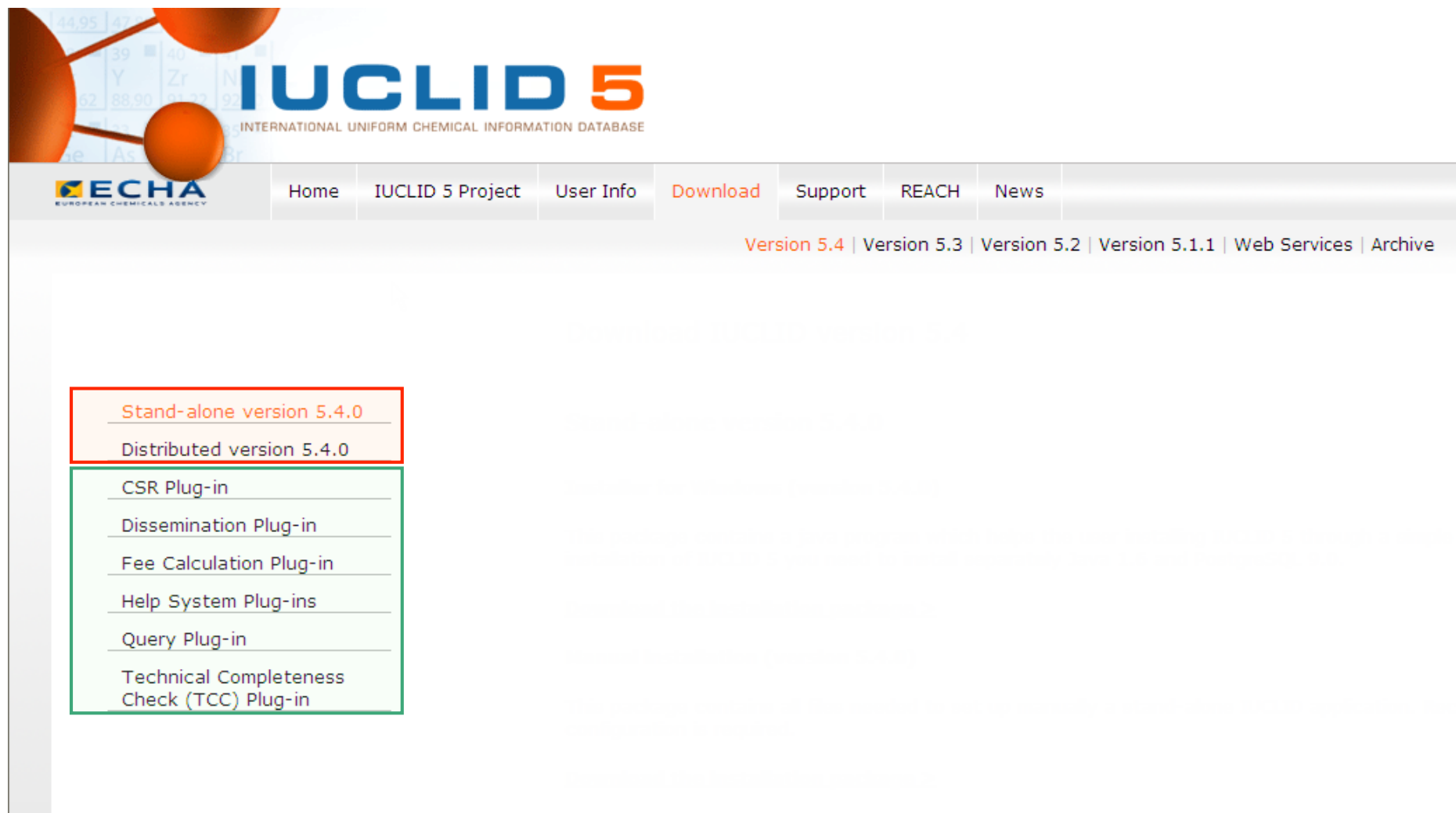
Where to get IUCLID 5

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



also accessible via the ECHA website



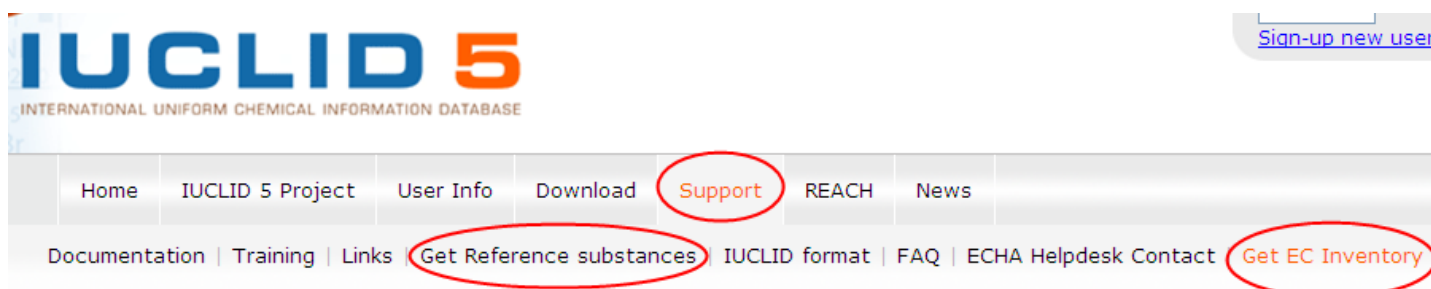


The screenshot shows the IUCLID 5 website. At the top left is the ECHA logo. The main header features the IUCLID 5 logo and the text 'INTERNATIONAL UNIFORM CHEMICAL INFORMATION DATABASE'. Below this is a navigation menu with links for Home, IUCLID 5 Project, User Info, Download (highlighted in red), Support, REACH, and News. Under the 'Download' link, there are sub-links for Version 5.4, Version 5.3, Version 5.2, Version 5.1.1, Web Services, and Archive. On the left side of the page, there is a list of download options, with the first two highlighted in red and the remaining five in green:

- Stand-alone version 5.4.0
- Distributed version 5.4.0
- CSR Plug-in
- Dissemination Plug-in
- Fee Calculation Plug-in
- Help System Plug-ins
- Query Plug-in
- Technical Completeness Check (TCC) Plug-in

EC inventory and reference substances

- Download from the IUCLID website



Get EC Inventory

In your work with IUCLID 5, you will see that the system will often prompt you for 'EC inventory' information. The EC Inventory is a list of substance identities which is based on a combination of the following EU inventories: EINECS, ELINCS and NLP-list. It is recommended to download and import the complete EC inventory into your IUCLID 5 installation. Please go to the link below to do so.

Download [EC Inventory version 1.2 \(English\)](#)

Import

To import the new EC inventory and/or the 'list numbers' into your IUCLID installation:

- Open IUCLID
- On the 'Home' page presented after login, click the 'Import' link under Import in the Task panel
- The Import assistant comes up; select the input path and the file containing the new EC inventory
- Click the 'Finish' button to launch the import

Structure and main elements of IUCLID 5



Structure of IUCLID 5

IUCLID 5.4.0

File Edit Go Window Help Plugins

(Search by UUID)

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 - SID, literature references

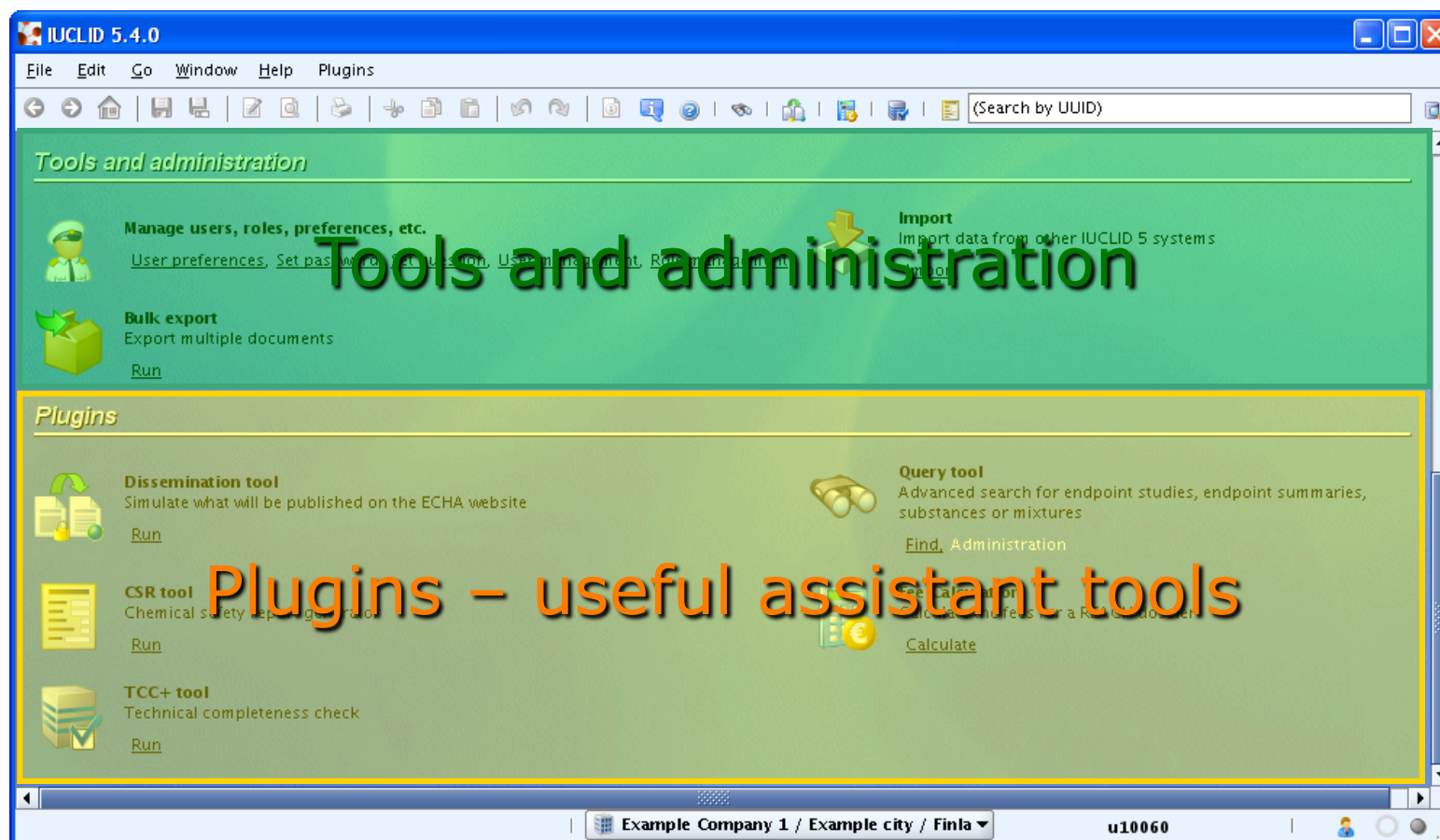
Tools and administration

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

Tools and administration

Example Company 1 / Example city / Finla | u10060

Structure of IUCLID 5



IUCLID structure

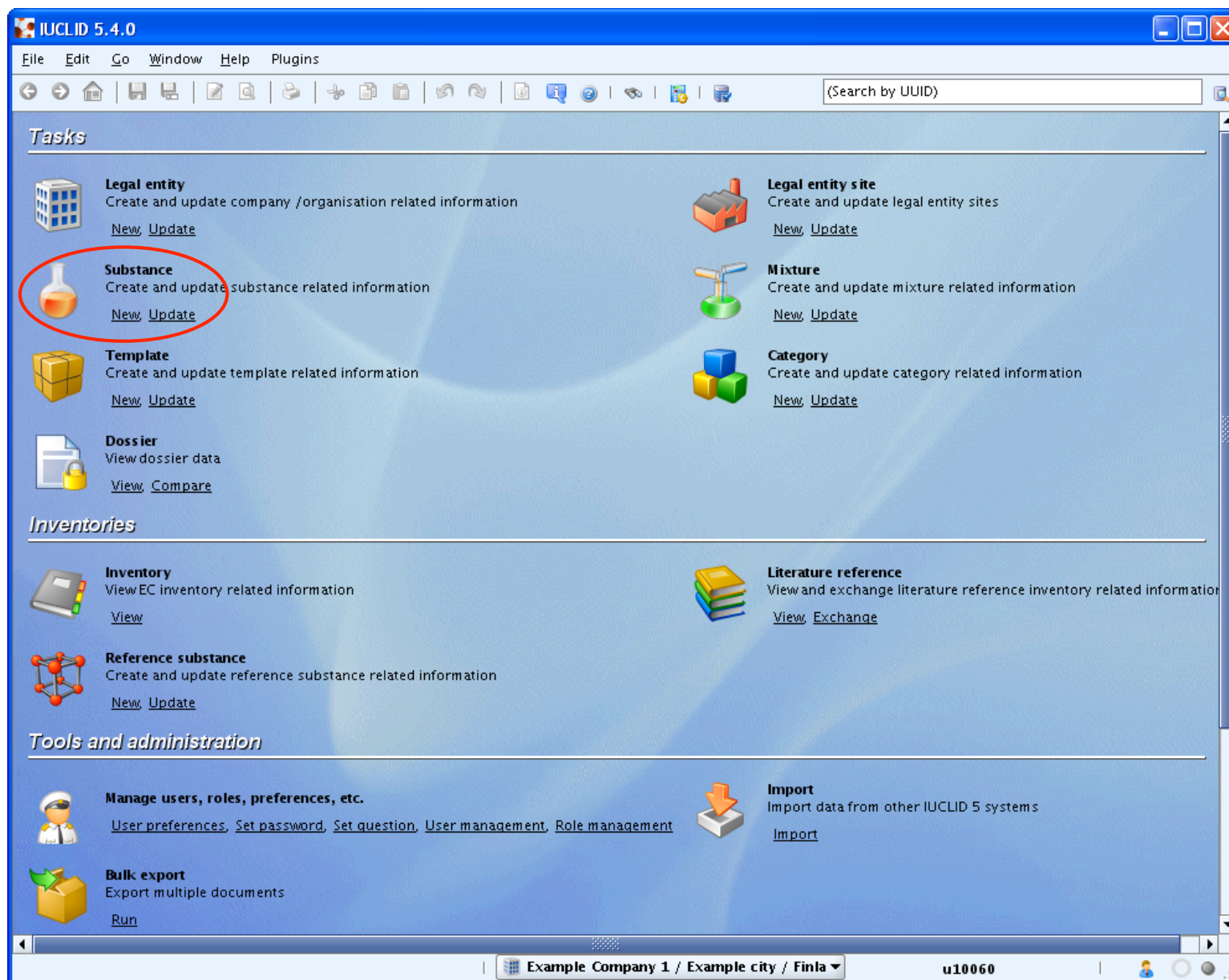
The screenshot displays the IUCLID 5.4.0 interface. On the left, a 'Query' tree view is highlighted with a red border, listing various substances such as Acetone, ethanol, and formamide. The main area is divided into several sections:

- Substance identification:** Fields for Chemical name (Example substance), Public name, Legal entity flags, Legal entity (Example Company 1 / Example city / Finland), Third party flags, and Third party.
- Role in the supply chain:** Role flags section with a checked 'Manufacturer' role and an unchecked 'Downstream user' role.
- Reference substance:** A table listing reference substances:

EC number	EC name
200-578-6	ethanol
CAS number	CAS name
64-17-5	ethanol
IUPAC name	ethanol
- Information:** A green section at the bottom containing tabs for Consultation, Attachments, Annotations, and Validation. It shows fields for Type (Substance), UUID (IUC5-c24406c8-5b0f-46fe-8fa9-310f8e6c24fe), and Dossier UUID (0).

Overlaid text labels identify the 'Query & Tree view' (red), 'Data area' (blue), and 'Information' (green) sections.

IUCLID Substance dataset



IUCLID 5.4.0

File Edit Go Window Help Plugins

(Search by UUID)

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](#)

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](#)

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](#)

Example Company 1 / Example city / Finla u10060

IUCLID Substance dataset

- The Substance dataset  is the core of information in IUCLID;
- Repository of data, which is used to create a Dossier for the substance to be registered;
- Contains all data related to a chemical substance:
 - chemical identity, including the substance composition
 - information on the classification and labelling
 - information on manufacture, use and exposure
 - all required and available (robust) study summaries
 - the Chemical Safety Report (if required)

Structure of IUCLID 5

IUCLID 5.4.0

File Edit Go Window Help Plugins

(Search by UUID)

Tasks

- Legal entity**
Create and update company /organisation related information
[New](#) [Update](#)
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Create and update substance related information
[New](#) [Update](#)
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Inventories

- Inventory**
View EC inventory related information
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View and exchange literature reference inventory related information
[View](#) [Exchange](#)

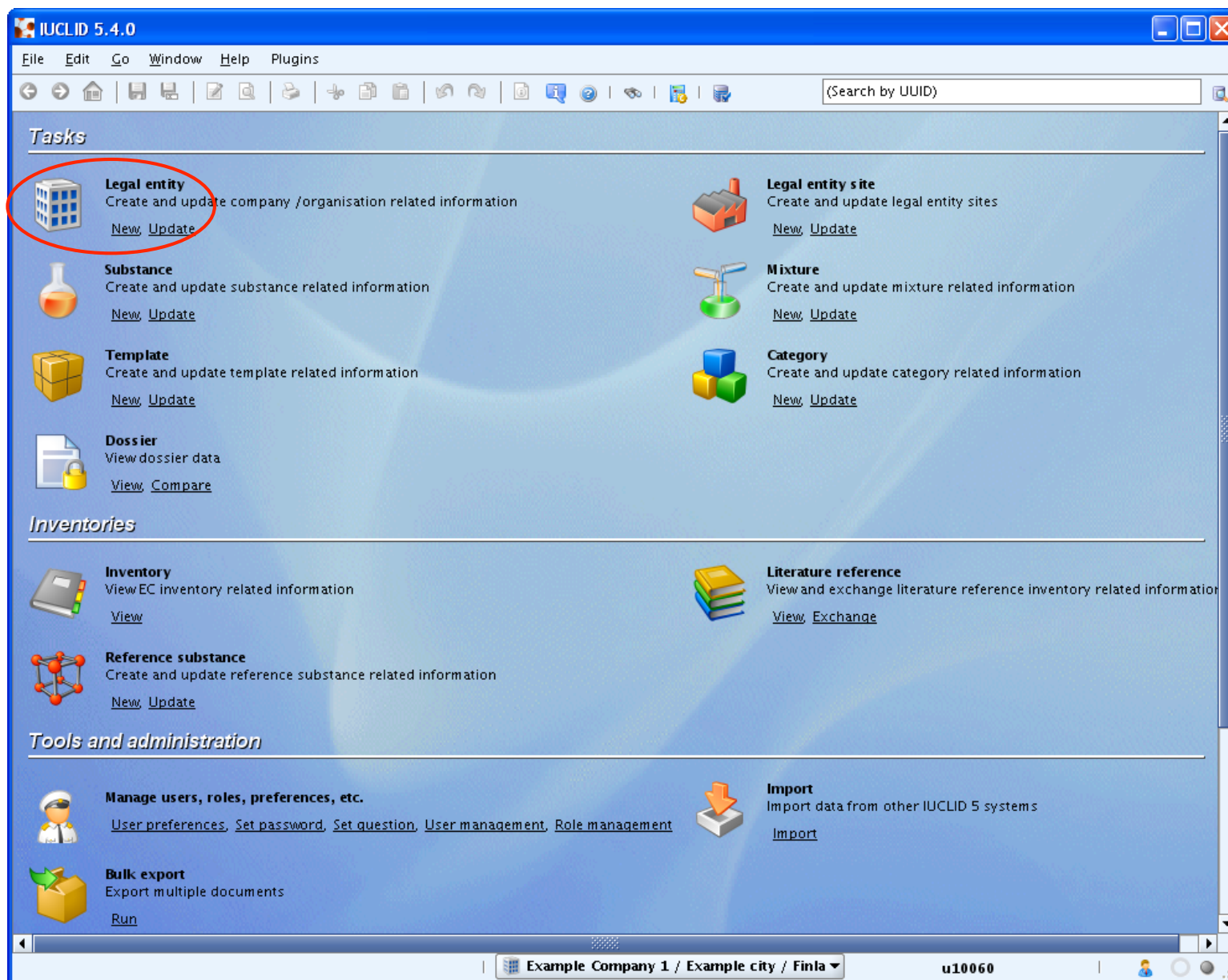
Tools and administration

- 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](#)

Substance identity

Example Company 1 / Example city / Finla u10060

IUCLID Legal entity




The screenshot displays the IUCLID 5.4.0 software interface. The window title is "IUCLID 5.4.0". The menu bar includes "File", "Edit", "Go", "Window", "Help", and "Plugins". The toolbar contains various icons for navigation and file management, along with a search box labeled "(Search by UUID)".

The main content area is organized into sections:

- Tasks**
 - Legal entity** (highlighted with a red circle): 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](#)
- 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](#)
- 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](#)

The status bar at the bottom shows "Example Company 1 / Example city / Finla" and "u10060".

IUCLID Legal entity

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

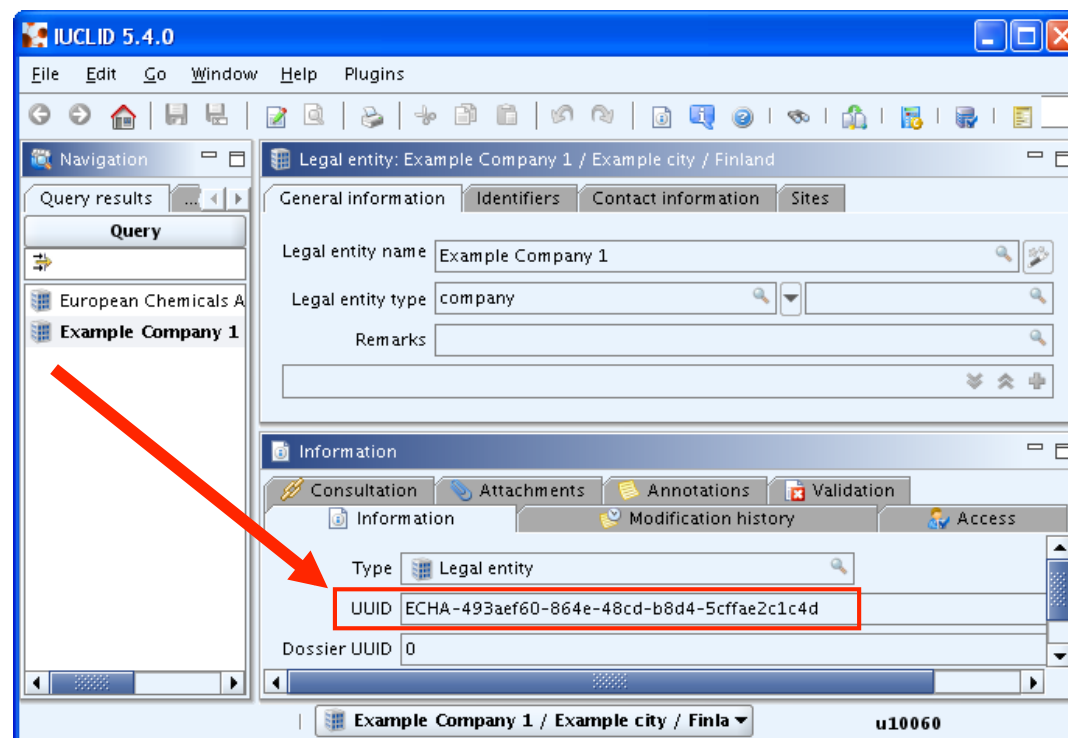
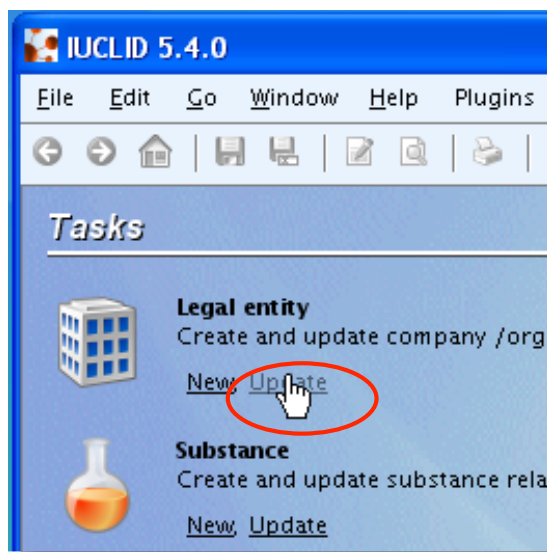
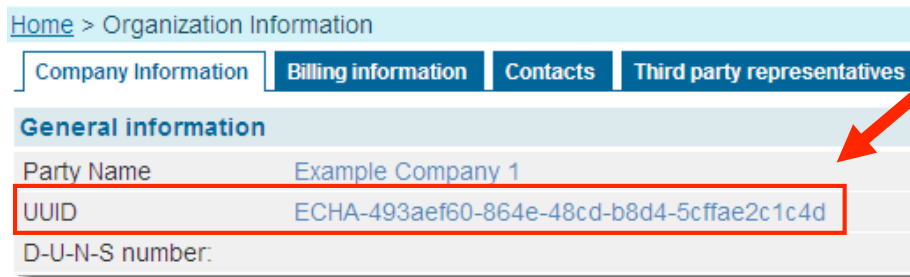
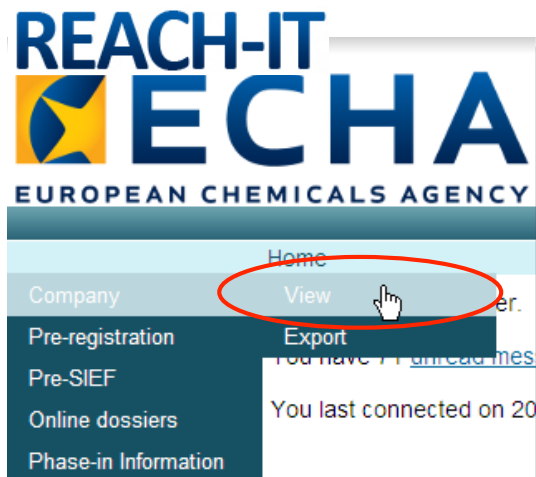
Legal entity – important!

1. Only official LEO are valid: LEOX file downloaded from REACH-IT or IUCLID website
2. Important that the same LEOX is used in all contexts. LEO must be synchronised between REACH-IT – IUCLID.

REACH-IT Industry User Manual 2

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

Synchronised Legal entity



Official Legal entity

- REACH-IT:



Welcome to REACH-IT

REACH-IT provides an online platform to submit data and dossier information to ECHA. REACH-IT to make non-confidential information on chemicals available to the public.

What can you do?

To login to REACH-IT you first need to sign-up and provide information on your identity. You can sign-up either as a company or as a third party.

- If you already have an account, you may [login](#) to the system.

If you have not created an account yet, you can do it here below.

- [Sign up as a company](#)
- [Sign up as a Data Holder](#)
- [Sign up as an interested third party](#)
- [Sign up as a third party representative](#)

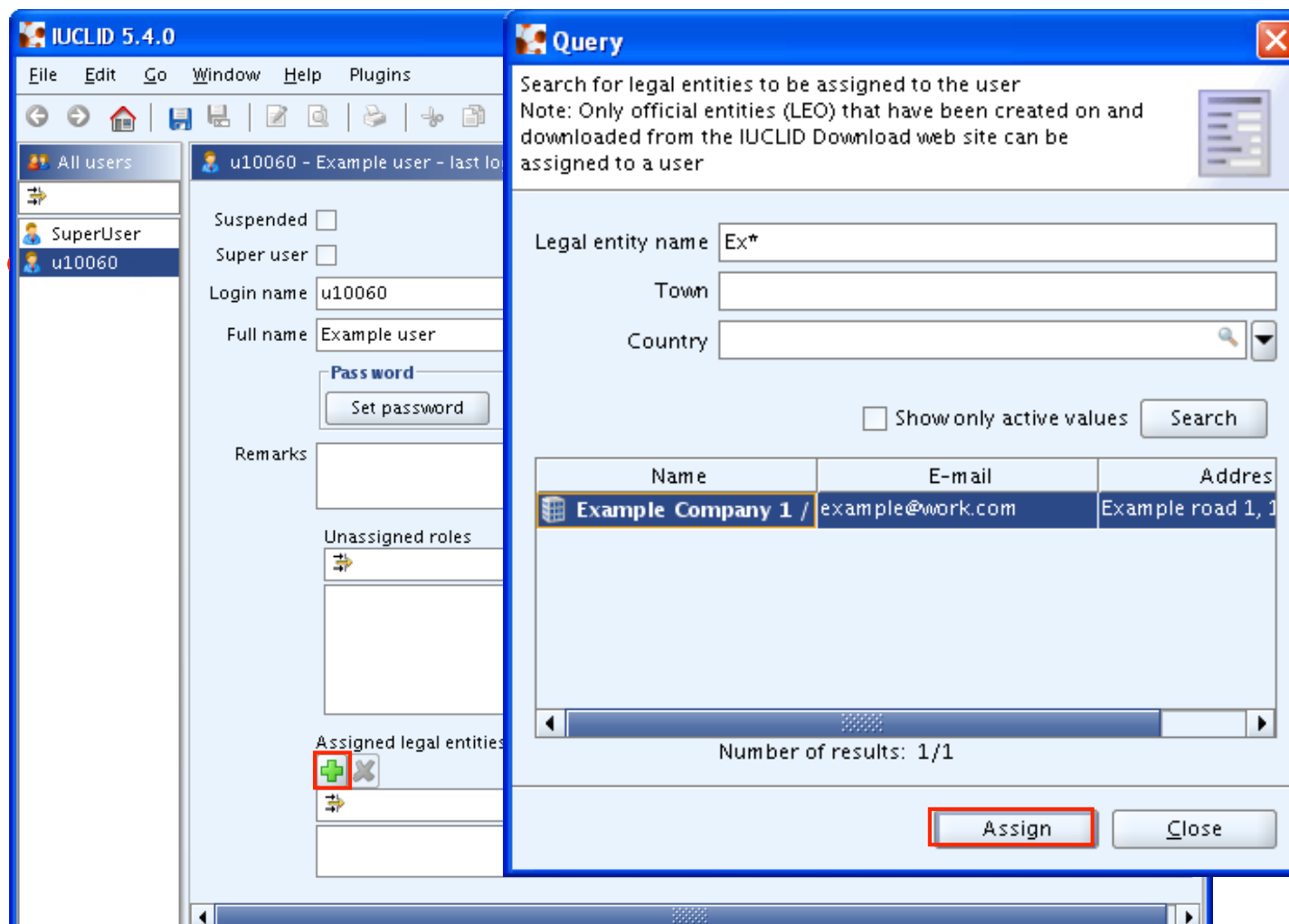


<filename>.i5z

IUCLID Legal entity

The screenshot displays the IUCLID 5.4.0 web application interface. The top navigation bar includes 'File', 'Edit', 'Go', 'Window', 'Help', and 'Plugins'. A search bar is labeled '(Search by UUID)'. The main content area is organized into sections: 'Tasks', 'Inventories', and 'Tools and administration'. Under 'Tasks', there are icons and descriptions for 'Legal entity', 'Substance', 'Template', 'Dossier', 'Legal entity site', 'Mixture', and 'Category'. Under 'Inventories', there are 'Inventory' and 'Reference substance'. Under 'Tools and administration', there are 'Manage users, roles, preferences, etc.' and 'Bulk export'. The 'User management' link in the 'Manage users...' section is circled in red. A red arrow points from an external icon (a green box with a building and 'i5z') to the 'Legal entity' task icon.

IUCLID Legal entity



The screenshot shows the IUCLID 5.4.0 application window. On the left, a user list includes 'All users', 'SuperUser', and 'u10060'. The main area displays the profile for user 'u10060 - Example user - last lo'. The profile includes fields for 'Suspended', 'Super user', 'Login name', 'Full name', 'Password', and 'Remarks'. Below these are sections for 'Unassigned roles' and 'Assigned legal entities'. A 'Query' dialog box is open in the foreground, titled 'Query'. It contains a search instruction: 'Search for legal entities to be assigned to the user. Note: Only official entities (LEO) that have been created on and downloaded from the IUCLID Download web site can be assigned to a user'. The search criteria include 'Legal entity name' (with 'Ex*' entered), 'Town', and 'Country'. There is a 'Search' button and a checkbox for 'Show only active values'. Below the search fields is a table with the following data:

Name	E-mail	Address
Example Company 1 /	example@work.com	Example road 1, 1

At the bottom of the dialog, it shows 'Number of results: 1/1' and two buttons: 'Assign' and 'Close'. The 'Assign' button is highlighted with a red box.

Structure of IUCLID 5

The screenshot displays the IUCLID 5.4.0 interface with the following sections and items:

- 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](#)
- 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](#)
- 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](#)

A central white oval labeled "Substance owner" is connected by red lines to the "Legal entity", "Substance", "Legal entity site", and "Mixture" items.

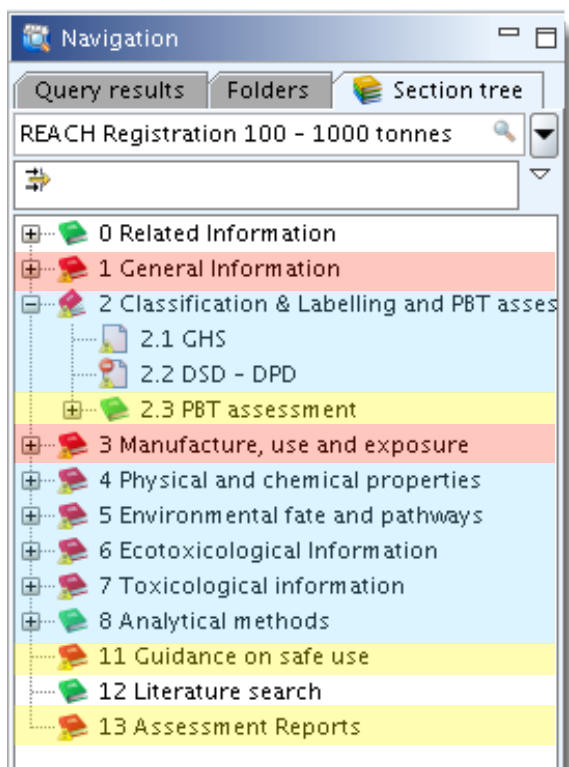
Filling in the substance dataset



Substance dataset – required information

- Own tonnage band(s) and JS tonnage band;
 - Highest information requirements must be covered
- Information requirements
 - REACH Articles 10–12 (standard), 17–19 (intermediates)
 - REACH Annex VI
 - REACH Annexes VII – X (tonnage dependent)
 - REACH Article 14 and Annex I (CSR)

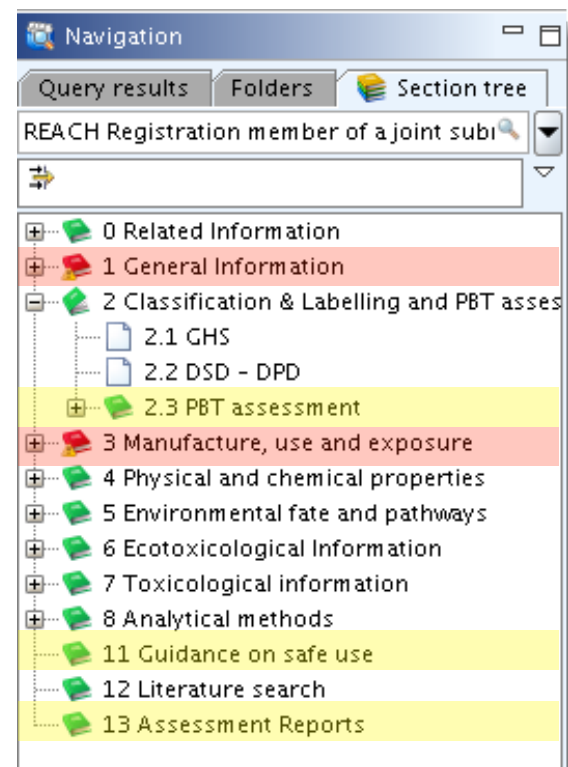
Substance dataset – Joint Submission



Information submitted by each registrant in their own dossier.

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

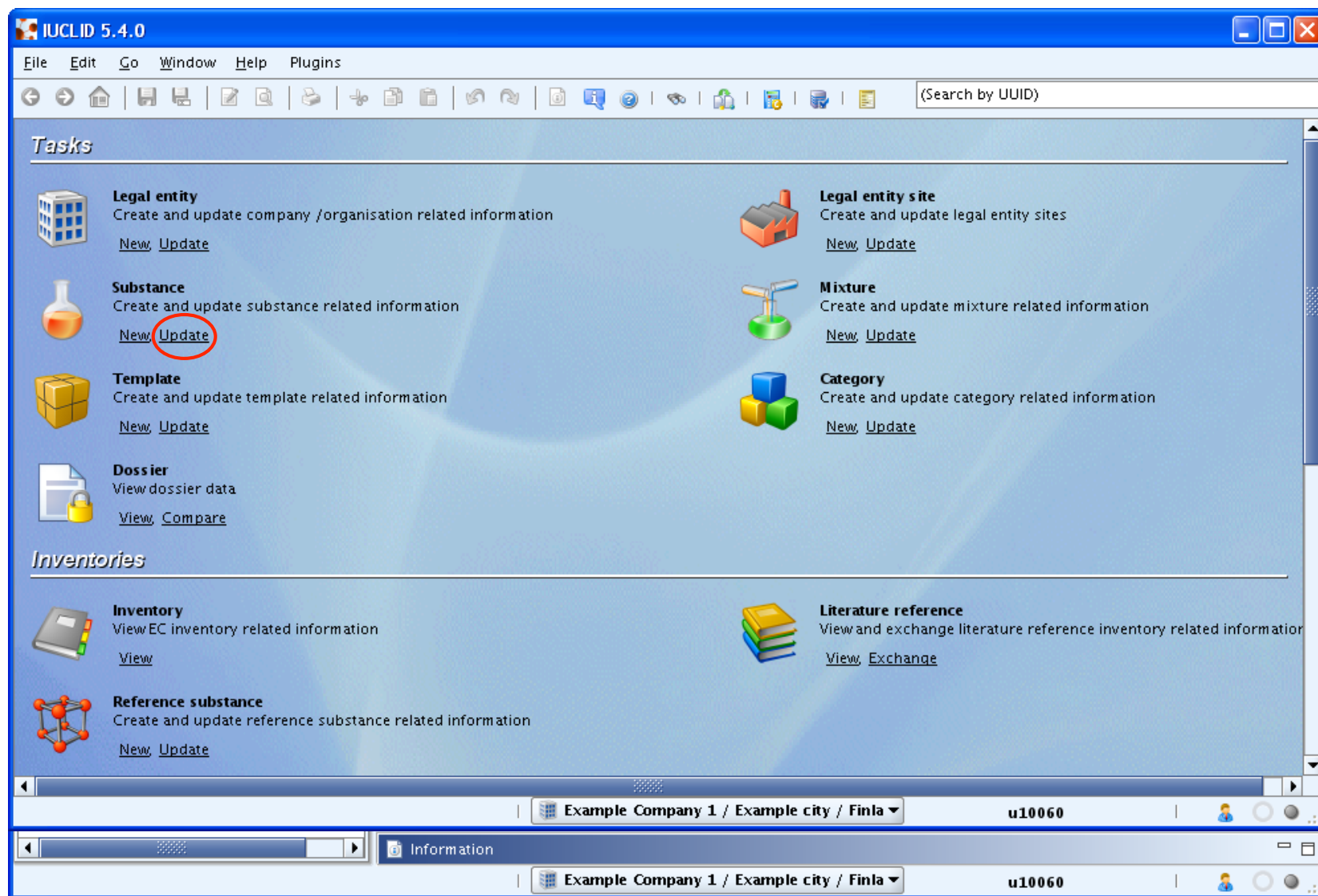
Information submitted by the LEAD on behalf of the JS, or individually by each registrant, according to agreement.



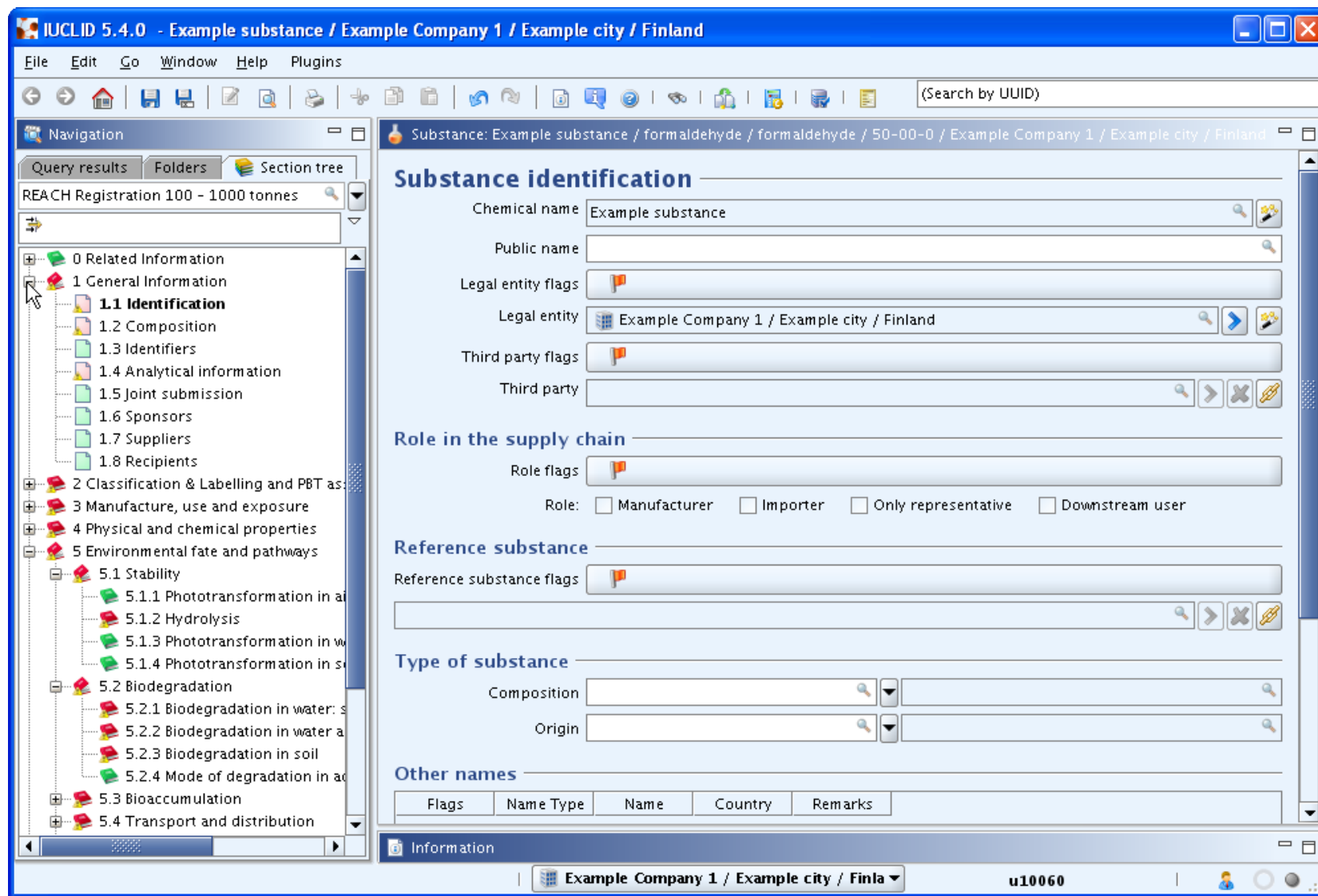
How to fill in a Substance dataset

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

Creation of a new Substance dataset



Creation of a new Substance dataset



The screenshot displays the IUCLID 5.4.0 software interface. The window title is "IUCLID 5.4.0 - Example substance / Example Company 1 / Example city / 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 tree structure of sections. The "1.1 Identification" section is selected. The tree includes:

- 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 as...
- 3 Manufacture, use and exposure
- 4 Physical and chemical properties
- 5 Environmental fate and pathways
 - 5.1 Stability
 - 5.1.1 Phototransformation in air
 - 5.1.2 Hydrolysis
 - 5.1.3 Phototransformation in water
 - 5.1.4 Phototransformation in soil
 - 5.2 Biodegradation
 - 5.2.1 Biodegradation in water: surface
 - 5.2.2 Biodegradation in water: sediment
 - 5.2.3 Biodegradation in soil
 - 5.2.4 Mode of degradation in air
 - 5.3 Bioaccumulation
 - 5.4 Transport and distribution

The main area displays the "Substance identification" form for "Example substance / formaldehyde / formaldehyde / 50-00-0 / Example Company 1 / Example city / Finland". The form includes the following fields:

- Chemical name:** Example substance
- Public name:** (empty)
- Legal entity flags:** (empty)
- Legal entity:** Example Company 1 / Example city / Finland
- Third party flags:** (empty)
- Third party:** (empty)
- Role in the supply chain:**
 - Role flags:** (empty)
 - Role:** Manufacturer Importer Only representative Downstream user
- Reference substance:**
 - Reference substance flags:** (empty)
- Type of substance:**
 - Composition:** (empty)
 - Origin:** (empty)
- Other names:** (empty)

At the bottom, there is an "Information" pane with a table header:

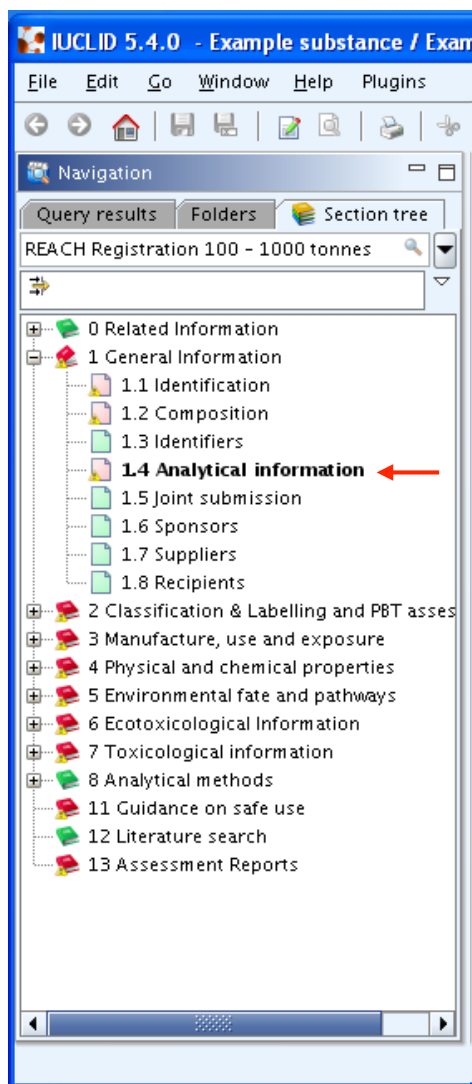
Flags	Name Type	Name	Country	Remarks

The status bar at the bottom shows "Example Company 1 / Example city / Finla" and "u10060".

How to fill in a Substance dataset

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

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

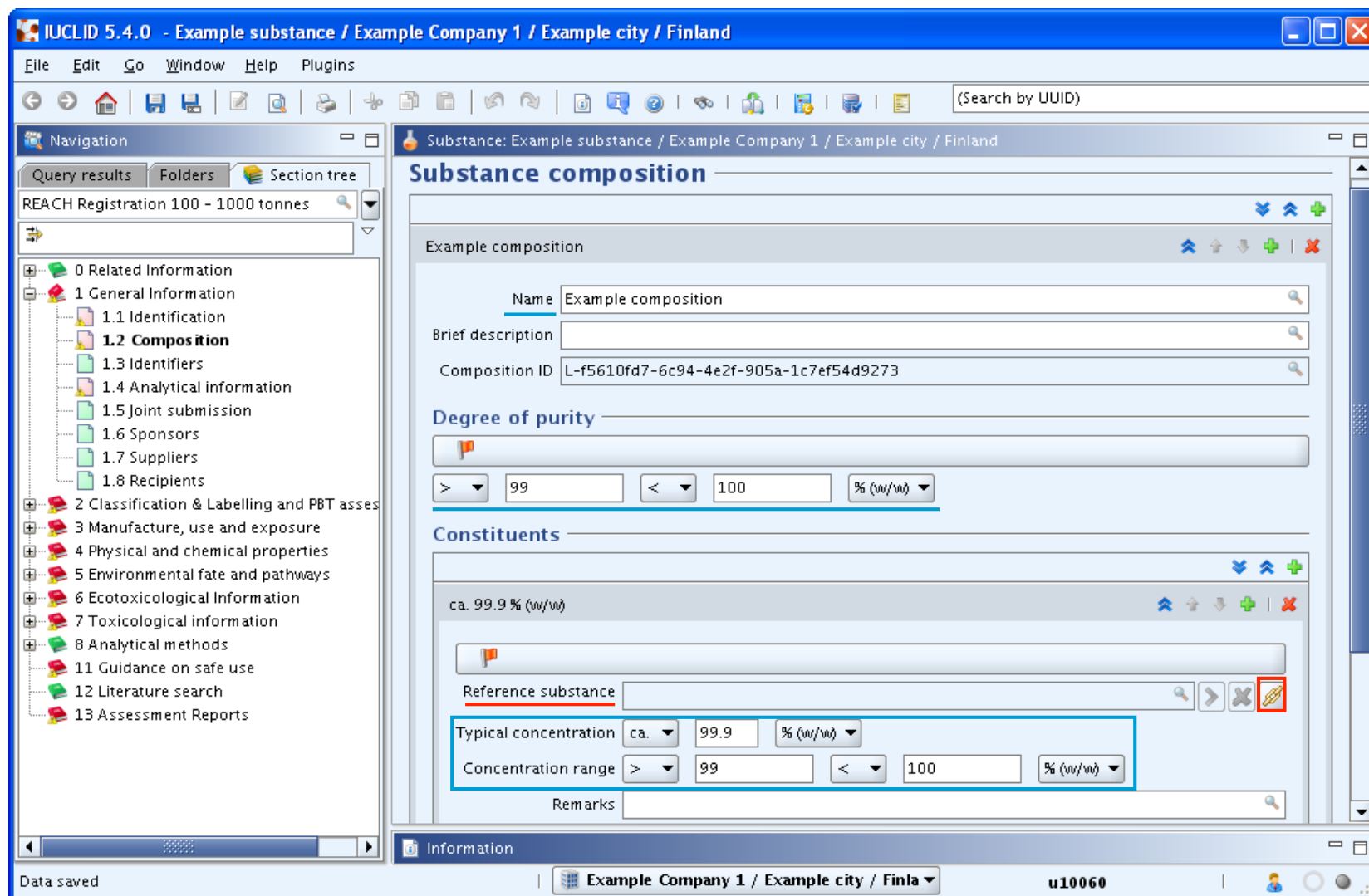
Guidance for identification and naming of substances under REACH and CLP

Sections 1.1 and 1.2 – Reference substance

The screenshot displays the IUCLID 5.4.0 software interface. The title bar reads "IUCLID 5.4.0 - Example substance / Example Company 1 / Example city / Finland". The main window is divided into several panes:

- Navigation Pane (Left):** Shows a tree structure of sections. Section 1.1 "Identification" is highlighted with a red arrow. Other sections include 0 Related Information, 1 General Information, 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, and 13 Assessment Reports.
- Main Content Area (Right):** Displays the "Substance identification" section. It contains several data entry fields:
 - Chemical name:** Example substance
 - Public name:** (empty)
 - Legal entity flags:** (empty)
 - Legal entity:** Example Company 1 / Example city / Finland
 - Third party flags:** (empty)
 - Third party:** (empty)
 - Role in the supply chain:** Role flags (empty). Role: Manufacturer Importer Only representative Downstream user
 - Reference substance:** Reference substance flags (empty)
 - Type of substance:** Composition (empty), Origin (empty)
 - Other names:** (empty)
- Bottom Status Bar:** Shows "Switched to edit mode", "Example Company 1 / Example city / Finla", and "u10060".

Sections 1.1 and 1.2 – Reference substance



The screenshot displays the IUCLID 5.4.0 software interface. The main window title is "IUCLID 5.4.0 - Example substance / Example Company 1 / Example city / Finland". The left sidebar shows a navigation tree with sections 0 through 13. Section 1.2, "Composition", is highlighted. The main content area is titled "Substance composition" and contains the following fields and controls:

- Example composition** (Section header)
- Name:** Example composition
- Brief description:** (Empty text field)
- Composition ID:** L-f5610fd7-6c94-4e2f-905a-1c7ef54d9273
- Degree of purity:** (Section header)
- Purity range:** > 99 < 100 % (w/w)
- Constituents** (Section header)
- ca. 99.9 % (w/w)** (Section header)
- Reference substance:** (Text field with a red box around it)
- Typical concentration:** ca. 99.9 % (w/w)
- Concentration range:** > 99 < 100 % (w/w)
- Remarks:** (Text field)

The bottom status bar shows "Data saved", "Example Company 1 / Example city / Finla", and "u10060".

Linking an existing Reference substance

Query Find the reference substance

Reference substance name

CAS number (EC Inventory)

EC name

EC number

CAS number

CAS name

IUPAC name





Synonyms

SMILES notation

Molecular formula

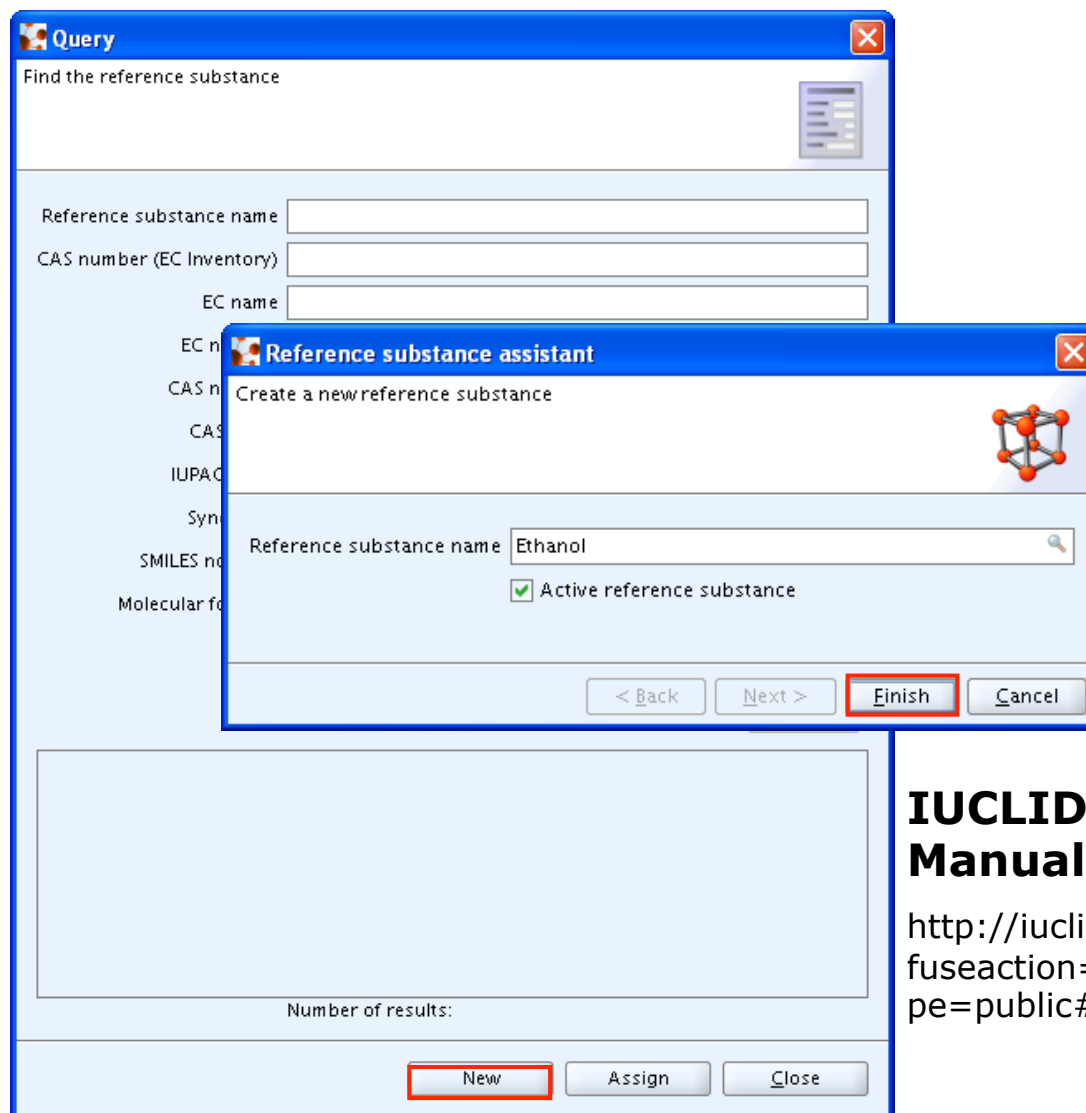
InChI

Show only active values

Name ▲	UUID	Remarks	Last modification ...
 ethane / ethane / 74-8...	EC85-e0251c27-d...		2007-05-10
 ethanediylidenetetrakis...	EC85-b27380d0-...		2007-05-10
 ethanethiol / ethanethi...	EC85-778feb3c-9...		2007-05-10
 ethanol / ethanol / 64-1	EC85-7d5e370b-...		2007-05-10

Number of results: 4/4

Creating a new Reference substance



IUCLID 5 Getting Started Manual – chapter 3

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

IUCLID 5.4.0 - Example substance / Ethanol / Example Company 1 / Example city / Finland

File Edit Go Window Help Plugins

(Search by UUID)

Navigation

Query results Folders Section tree

REACH Registration 100 - 1000 tonnes

- 0 Related Information
- 1 General Information
 - 1.1 Identification
 - 1.2 Composition** ←
 - 1.3 Identifiers
 - 1.4 Analytical information
 - 1.5 Joint submission
 - 1.6 Sponsors
 - 1.7 Suppliers
 - 1.8 Recipients
- 2 Classification & Labelling and PBT asses
- 3 Manufacture, use and exposure
- 4 Physical and chemical properties
- 5 Environmental fate and pathways
- 6 Ecotoxicological information
- 7 Toxicological information
- 8 Analytical methods
- 11 Guidance on safe use
- 12 Literature search
- 13 Assessment Reports

Substance: Example substance / Ethanol / Example Company 1 / Example city / Finland

Substance composition

Example composition

Name: Example composition

Brief description:

Composition ID: L-f5610fd7-6c94-4e2f-905a-1c7ef54d9273

Degree of purity

> 99 < 100 % (w/w)

Constituents

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

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

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

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

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

Remarks:

Impurities

+

Additives

+

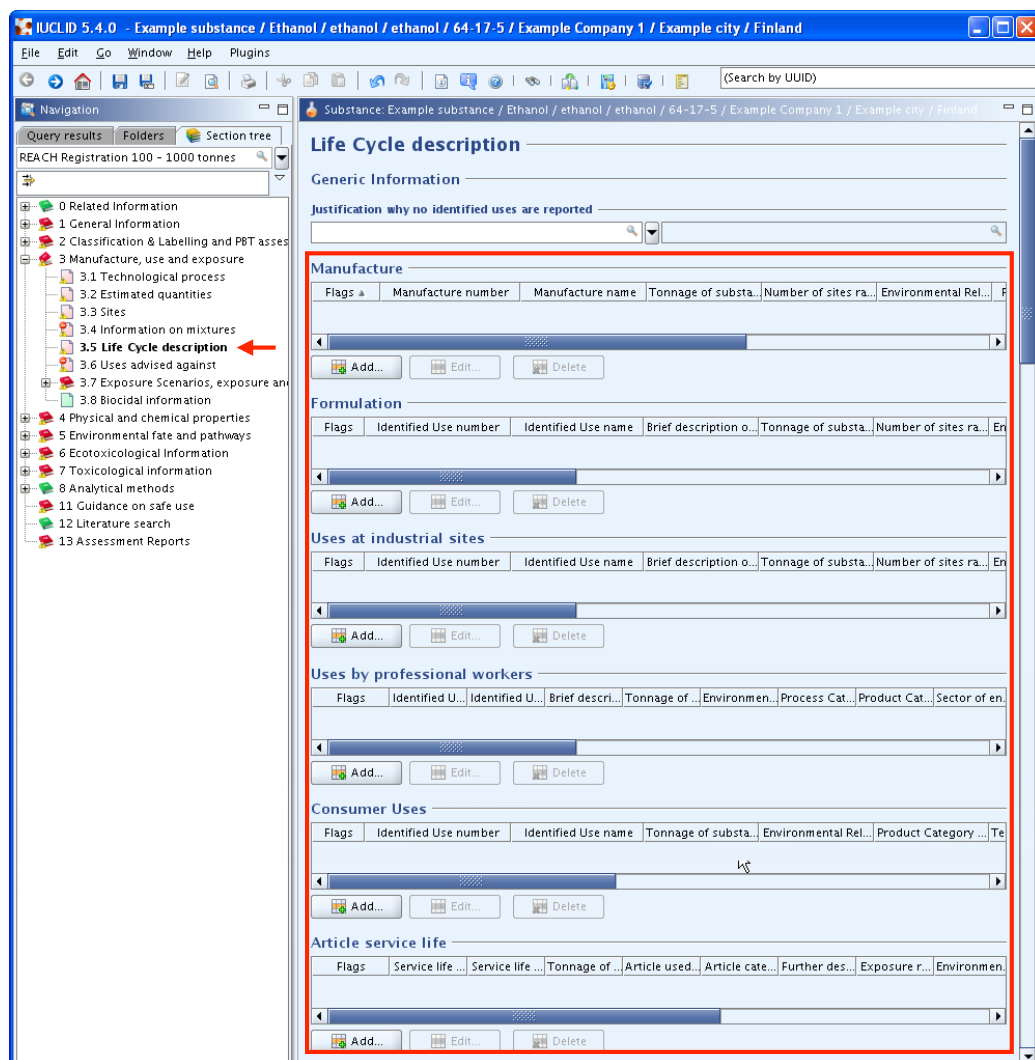
Information

Example Company 1 / Example city / Finla u10060

How to fill in a Substance dataset

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

Section 3.5 – use reporting by JS Lead



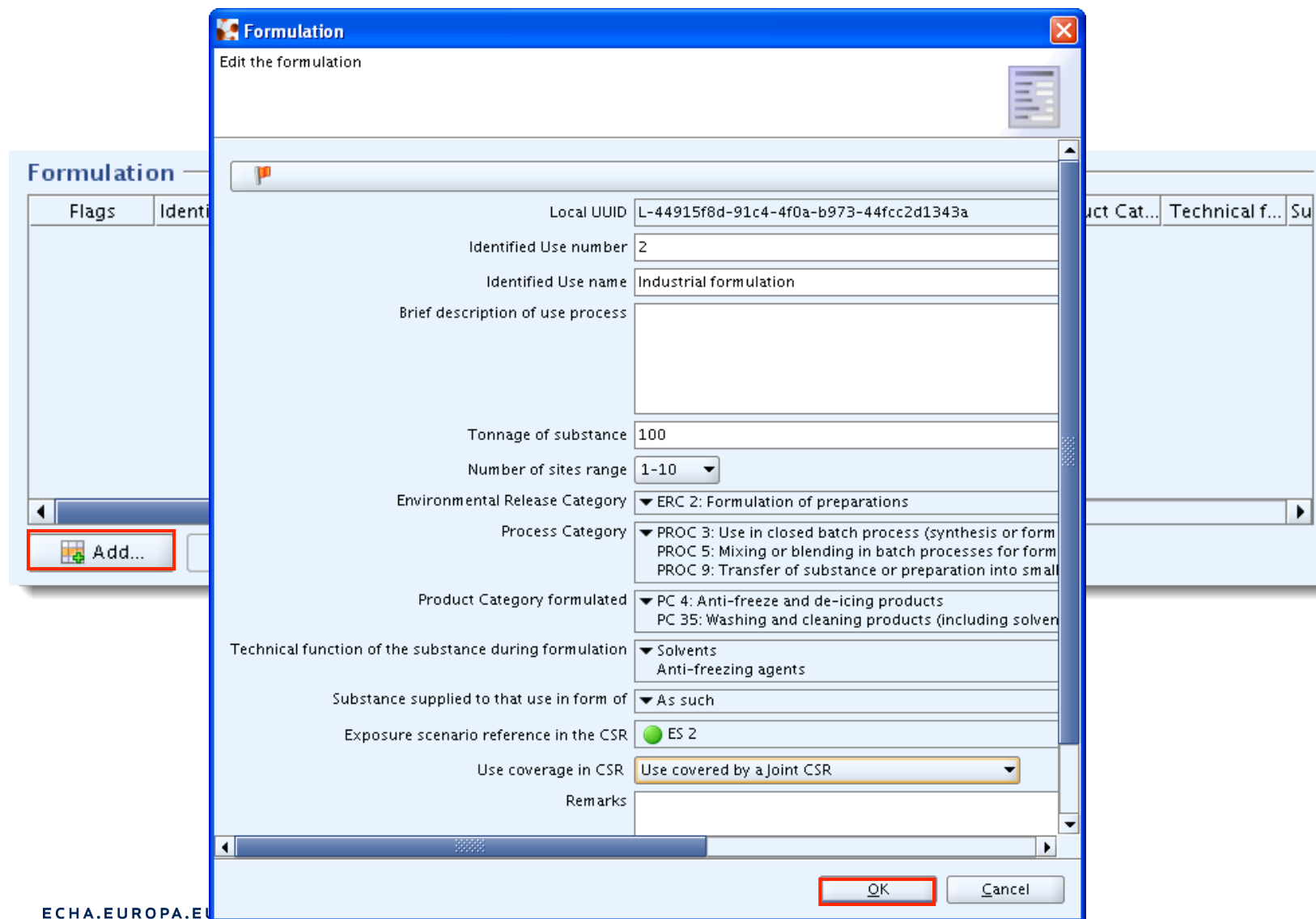
The screenshot shows the IUCLID 5.4.0 software interface. The title bar reads "IUCLID 5.4.0 - Example substance / Ethanol / ethanol / ethanol / 64-17-5 / Example Company 1 / Example city / Finland". The left sidebar shows a navigation tree with "3.5 Life Cycle description" highlighted by a red arrow. The main window displays the "Life Cycle description" section, which is outlined in red. This section includes several sub-sections, each with a table and "Add...", "Edit...", and "Delete" buttons:

- Generic Information**: Includes a search field for "Justification why no identified uses are reported".
- Manufacture**: Table with columns: Flags, Manufacture number, Manufacture name, Tonnage of substa..., Number of sites ra..., Environmental Rel... F.
- Formulation**: Table with columns: Flags, Identified Use number, Identified Use name, Brief description o..., Tonnage of substa..., Number of sites ra..., En.
- Uses at industrial sites**: Table with columns: Flags, Identified Use number, Identified Use name, Brief description o..., Tonnage of substa..., Number of sites ra..., En.
- Uses by professional workers**: Table with columns: Flags, Identified U..., Identified U..., Brief descri..., Tonnage of ..., Environmen..., Process Cat..., Product Cat..., Sector of en.
- Consumer Uses**: Table with columns: Flags, Identified Use number, Identified Use name, Tonnage of substa..., Environmental Rel..., Product Category ... Te.
- Article service life**: Table with columns: Flags, Service life ..., Service life ..., Tonnage of ..., Article used., Article cate..., Further des..., Exposure r..., Environmen.

Section 3.5 – use reporting by JS Lead

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

Section 3.5 – use reporting by JS Lead



The screenshot displays the 'Formulation' dialog box in the ECHA software. The dialog is titled 'Formulation' and contains the following fields and options:

- Local UUID:** L-44915f8d-91c4-4f0a-b973-44fcc2d1343a
- Identified Use number:** 2
- Identified Use name:** Industrial formulation
- Brief description of use process:** (Empty text area)
- Tonnage of substance:** 100
- Number of sites range:** 1-10
- Environmental Release Category:** ERC 2: Formulation of preparations
- Process Category:** PROC 3: Use in closed batch process (synthesis or form...
PROC 5: Mixing or blending in batch processes for form...
PROC 9: Transfer of substance or preparation into small...
- Product Category formulated:** PC 4: Anti-freeze and de-icing products
PC 35: Washing and cleaning products (including solven...
- Technical function of the substance during formulation:** Solvents
Anti-freezing agents
- Substance supplied to that use in form of:** As such
- Exposure scenario reference in the CSR:** ES 2
- Use coverage in CSR:** Use covered by a joint CSR
- Remarks:** (Empty text area)

At the bottom of the dialog, there are 'OK' and 'Cancel' buttons. In the background, another window titled 'Formulation' is visible, showing a table with columns 'Flags' and 'Identified Use'. An 'Add...' button is highlighted with a red box in the background window.

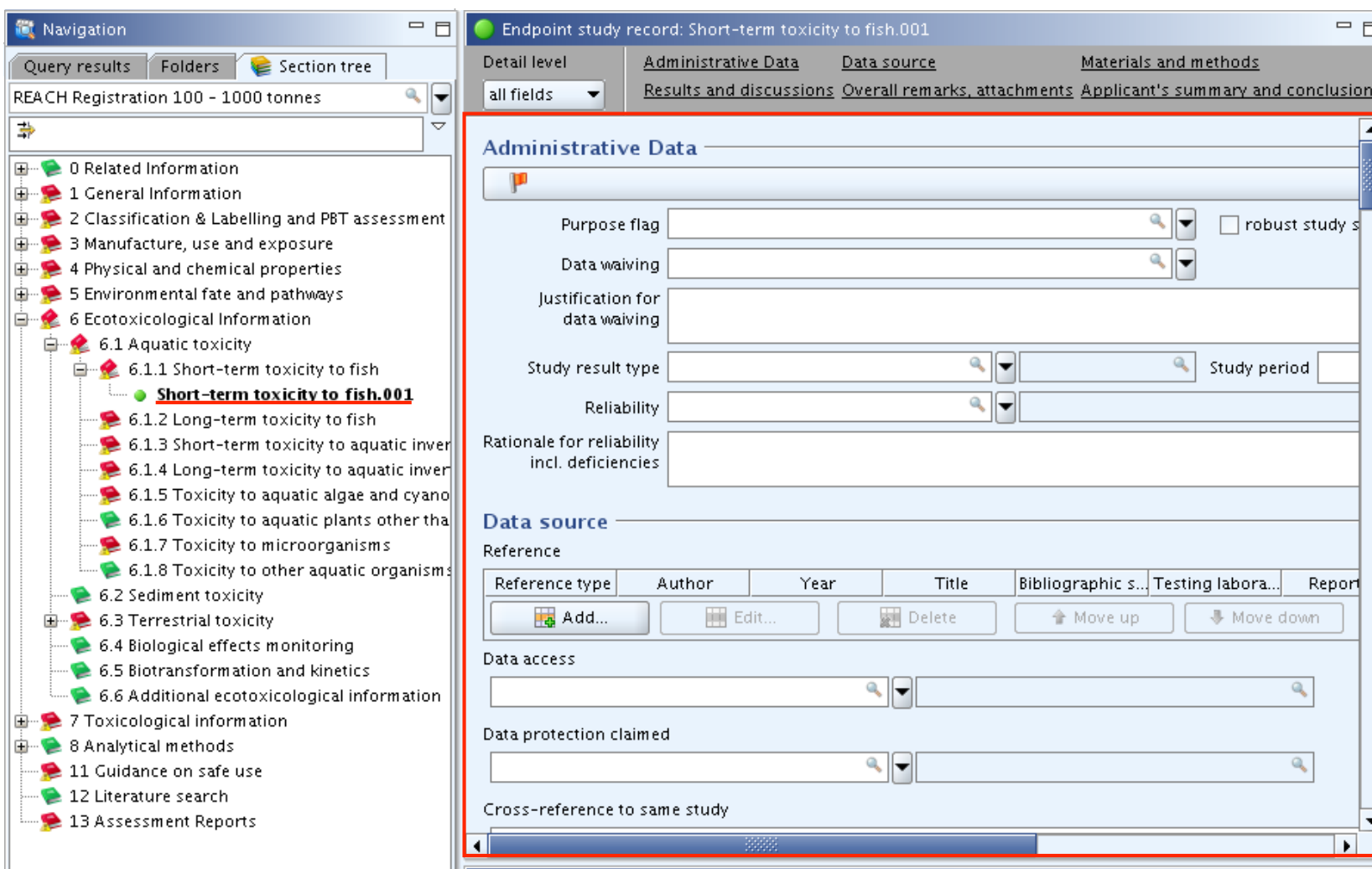
How to fill in a Substance dataset

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

Creation of 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



The screenshot displays the ECHA REACH registration system interface. On the left, a navigation pane shows a tree structure of registration sections. The right pane shows the 'Endpoint study record: Short-term toxicity to fish.001' form.

Navigation Pane (Left):

- 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
 - Short-term toxicity to fish.001** (Selected)
 - 6.1.2 Long-term toxicity to fish
 - 6.1.3 Short-term toxicity to aquatic inver
 - 6.1.4 Long-term toxicity to aquatic inver
 - 6.1.5 Toxicity to aquatic algae and cyano
 - 6.1.6 Toxicity to aquatic plants other tha
 - 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 Form (Right):

Endpoint study record: Short-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: [Text Field] [Search Icon] [Dropdown]
- robust study s
- Data waiving: [Text Field] [Search Icon] [Dropdown]
- Justification for data waiving: [Text Field]
- Study result type: [Text Field] [Search Icon] [Dropdown] Study period: [Text Field]
- Reliability: [Text Field] [Search Icon] [Dropdown]
- Rationale for reliability incl. deficiencies: [Text Field]

Data source

Reference

Reference type	Author	Year	Title	Bibliographic s...	Testing labora...	Report
<div style="display: flex; justify-content: space-between;"> Add... Edit... Delete Move up Move down </div>						

Data access: [Text Field] [Search Icon] [Dropdown] [Text Field] [Search Icon]

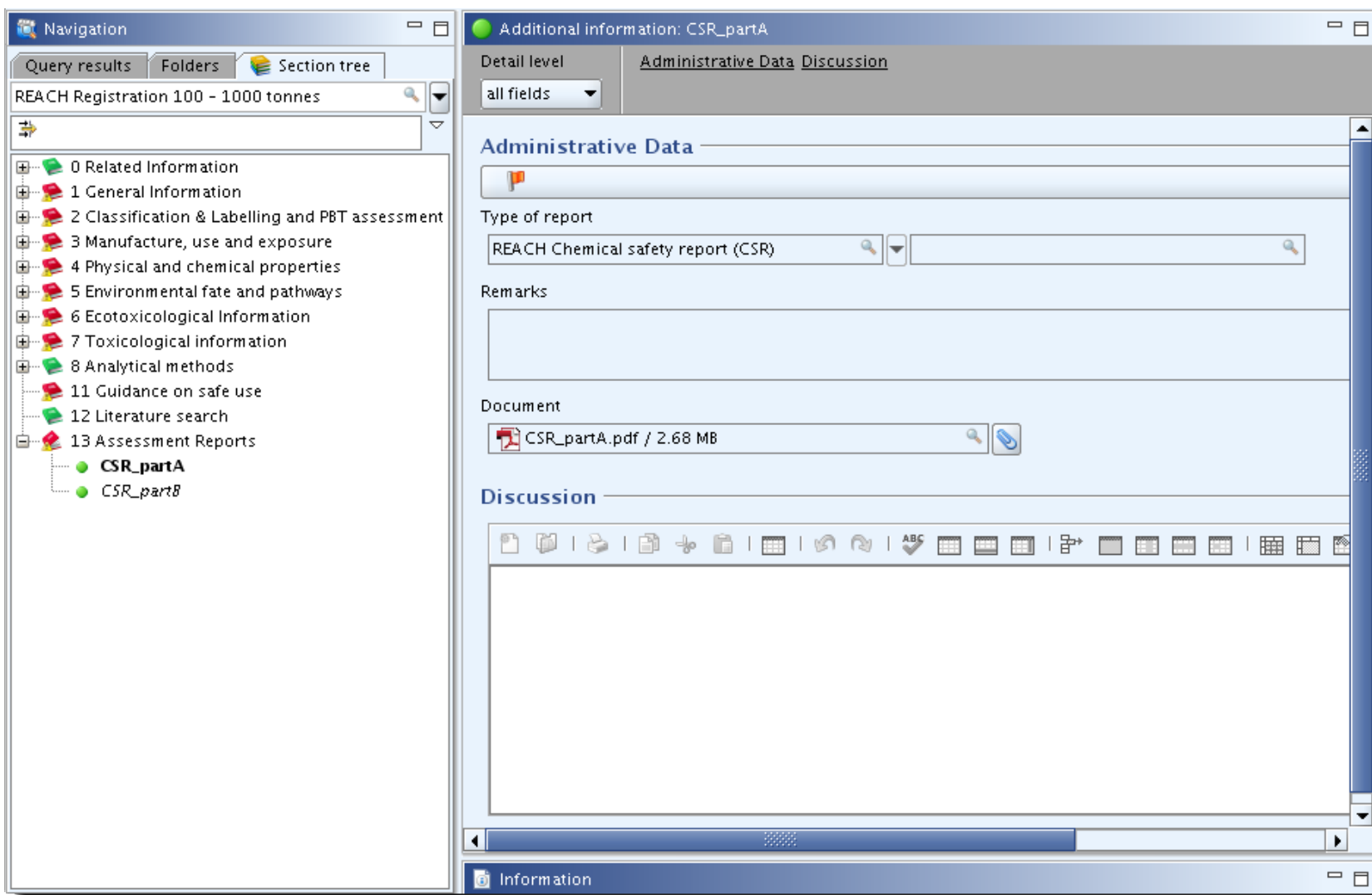
Data protection claimed: [Text Field] [Search Icon] [Dropdown] [Text Field] [Search Icon]

Cross-reference to same study: [Text Field]

How to fill in a Substance dataset

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

Section 13 – how to attach a CSR



The screenshot displays the ECHA REACH registration interface. On the left, the 'Navigation' pane shows a tree structure under 'REACH Registration 100 - 1000 tonnes'. The '13 Assessment Reports' folder is expanded, showing sub-items 'CSR_partA' and 'CSR_partB'. The main window, titled 'Additional information: CSR_partA', is divided into two tabs: 'Administrative Data' and 'Discussion'. The 'Administrative Data' tab is active and contains the following fields:

- Detail level:** Set to 'all fields'.
- Type of report:** A dropdown menu with 'REACH Chemical safety report (CSR)' selected.
- Remarks:** An empty text area.
- Document:** A field containing 'CSR_partA.pdf / 2.68 MB' with a paper icon and a blue attachment icon.

The 'Discussion' tab is currently empty and contains a rich text editor toolbar with various icons for text formatting and insertion. The bottom status bar of the window displays the word 'Information'.

Creating and exporting a dossier

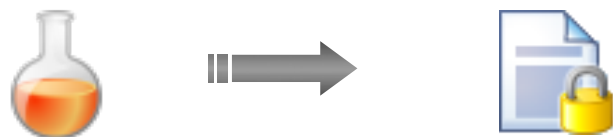
How to:

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



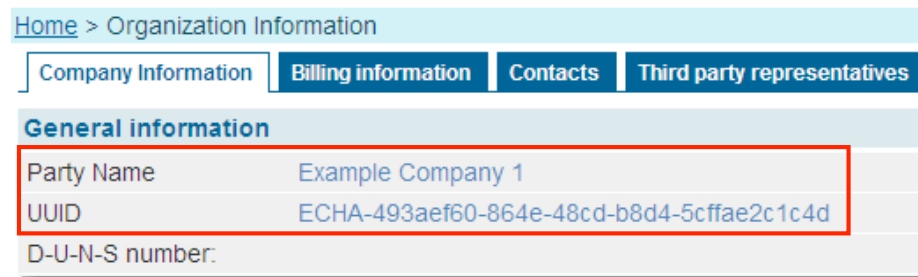
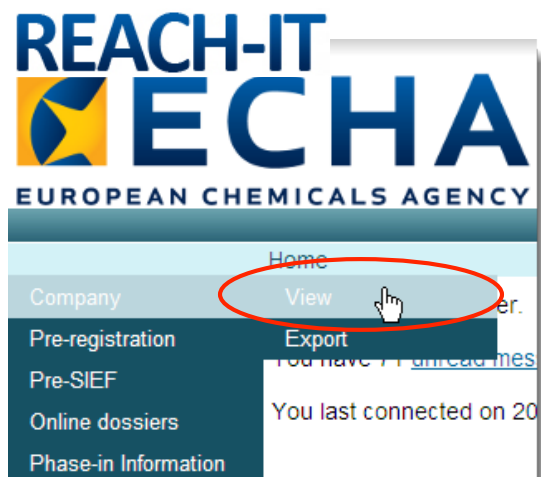
Creation of a JS lead IUCLID dossier

- Starting point is a complete Substance dataset;
 - all information required for JS tonnage band
- Dossier is created from the Substance dataset:
 - includes substance information
 - administrative information needed in submission
 - READ-ONLY, cannot be modified!
- The **dossier** is the document submitted to ECHA.



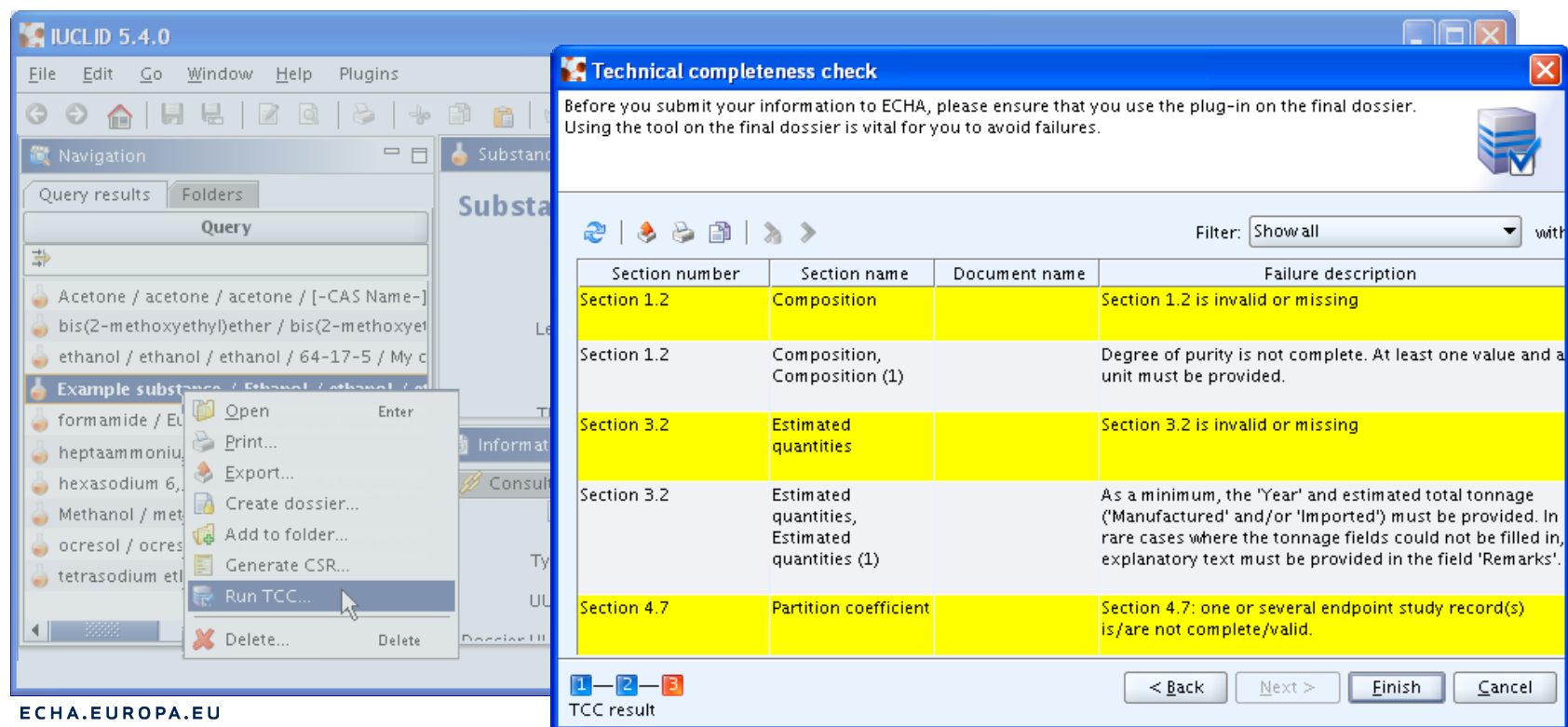
Before creating the dossier...

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



Before creating the dossier...

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



The screenshot shows the IUCLID 5.4.0 interface. In the background, a context menu is open over a substance entry, with 'Run TCC...' selected. In the foreground, the 'Technical completeness check' dialog box is displayed, showing a table of failure descriptions.

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

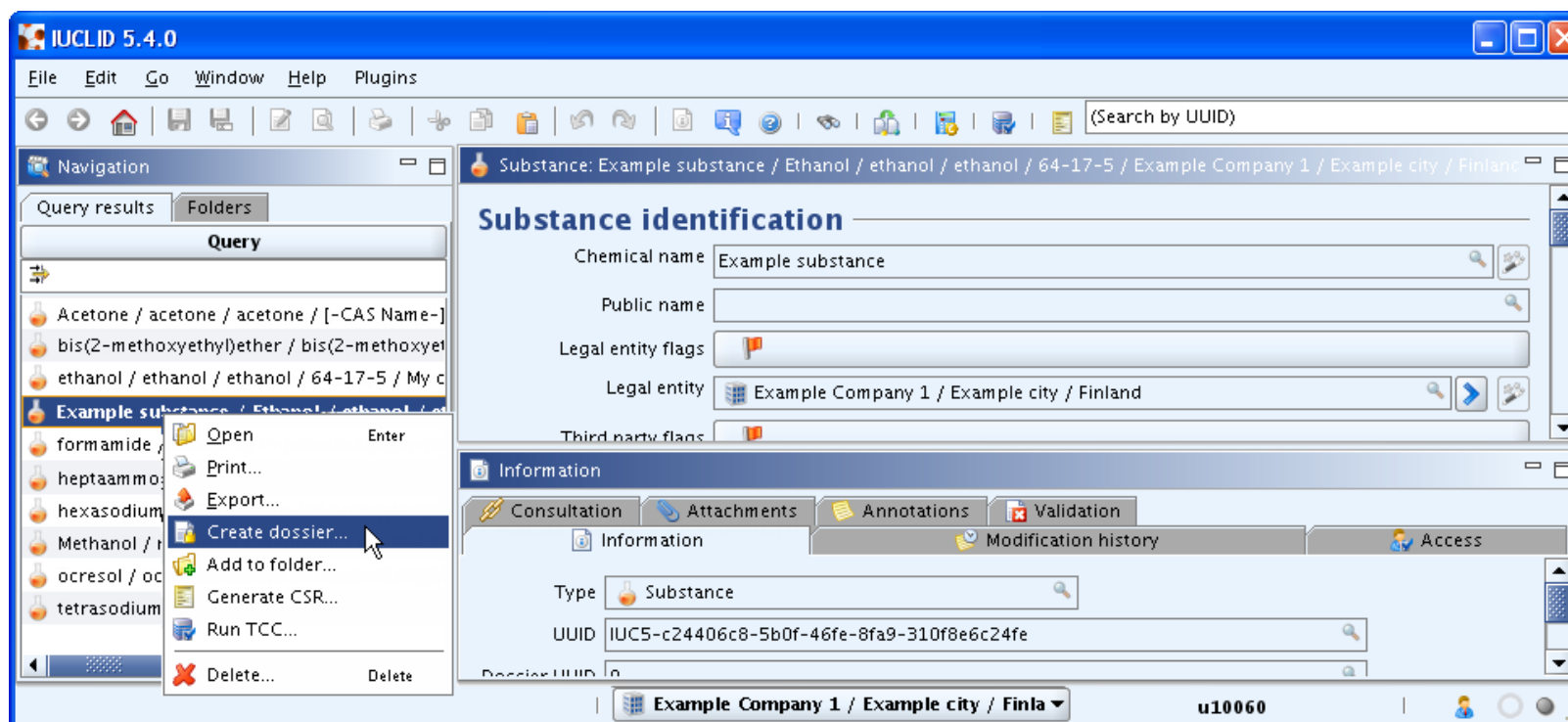
Section number	Section name	Document name	Failure description
Section 1.2	Composition		Section 1.2 is invalid or missing
Section 1.2	Composition, Composition (1)		Degree of purity is not complete. At least one value and a unit must be provided.
Section 3.2	Estimated quantities		Section 3.2 is invalid 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.

1 2 3
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!
- Include all information

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



The screenshot shows a software window titled "Dossier creation wizard". The window has a blue title bar and a close button in the top right corner. Below the title bar, there is a text area that reads: "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". To the right of this text is a document icon with a yellow padlock.

The main content area is divided into two sections:

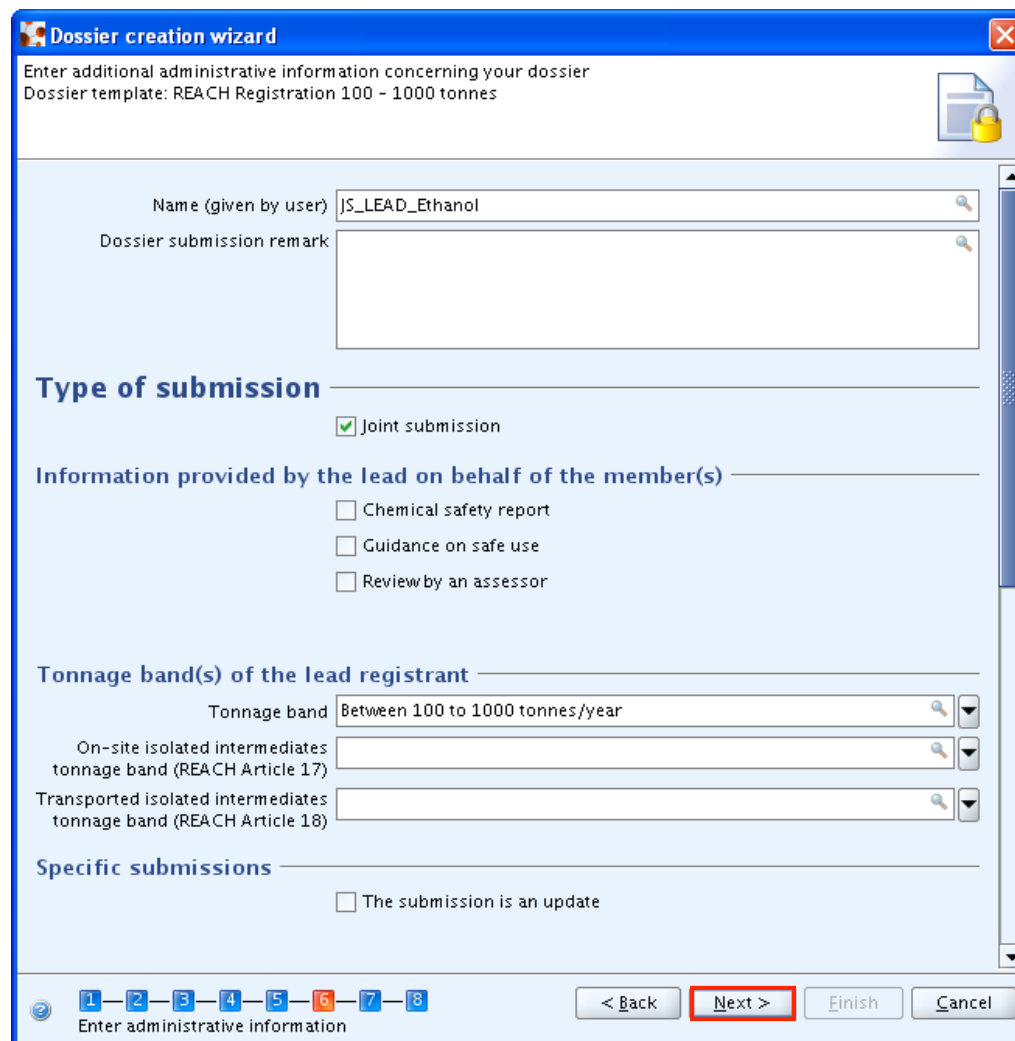
- Confidentiality**: This section has a "Deselect all" button and four checked checkboxes:
 - CBI - confidential business information
 - IP - intellectual property
 - no PA - not public available
 - Not confidential
- Use restricted to selected regulatory programmes**: This section has a "Deselect all" button and a list of checked checkboxes for various regulatory programs:
 - 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

At the bottom of the window, there is a note: "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". Below the note is a progress bar with six steps, where the first step is highlighted in blue. To the right of the progress bar are four buttons: "< Back", "Next >", "Finish", and "Cancel". At the very bottom, there is a small text label "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 on behalf of the members of the JS
- Complete dossier creation wizard

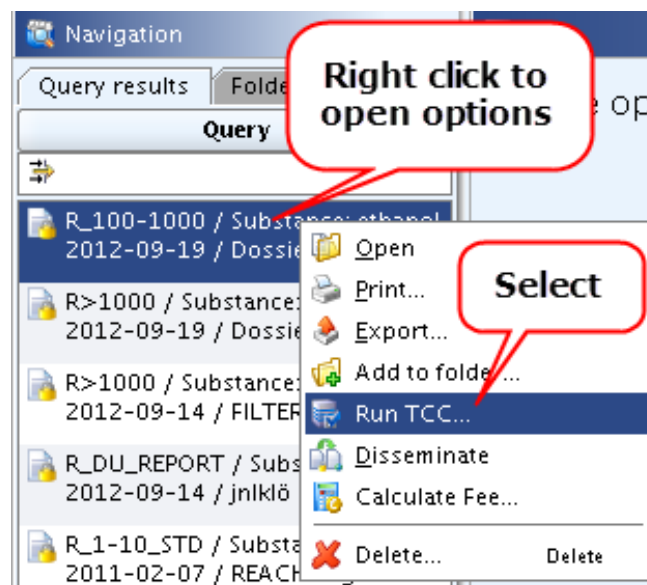
Data Submission Manual Part 5 -
How to Complete a Technical
Dossier for Registrations and
PPORD Notifications



The screenshot shows a software window titled "Dossier creation wizard" with a close button in the top right corner. The window contains the following elements:

- Title bar:** "Dossier creation wizard" with a close button (X).
- Header:** "Enter additional administrative information concerning your dossier" and "Dossier template: REACH Registration 100 - 1000 tonnes".
- Form fields:**
 - "Name (given by user)": A text box containing "JS_LEAD_Ethanol".
 - "Dossier submission remark": A large empty text area.
 - "Type of submission": A section with a checked checkbox for "Joint submission".
 - "Information provided by the lead on behalf of the member(s)": A section with three unchecked checkboxes: "Chemical safety report", "Guidance on safe use", and "Review by an assessor".
 - "Tonnage band(s) of the lead registrant": A section with three dropdown menus. The first is set to "Between 100 to 1000 tonnes/year". The other two are empty.
 - "Specific submissions": A section with an unchecked checkbox for "The submission is an update".
- Navigation:** A progress bar at the bottom shows 8 steps, with step 6 highlighted in red. To the right are buttons for "< Back", "Next >" (highlighted with a red box), "Finish", and "Cancel".

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



What if there are BR / TCC failures?

- Correct the missing / incomplete data in the substance dataset
- Create a dossier again
- Dossier can NOT be modified

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 type failure, warning

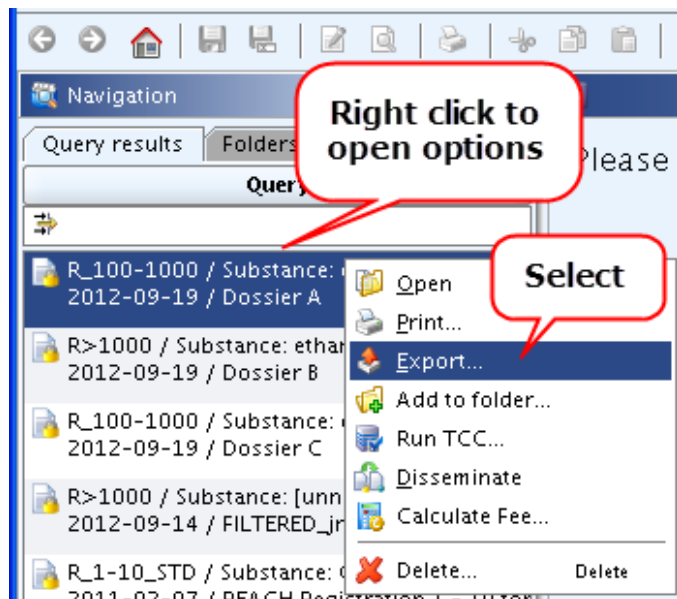
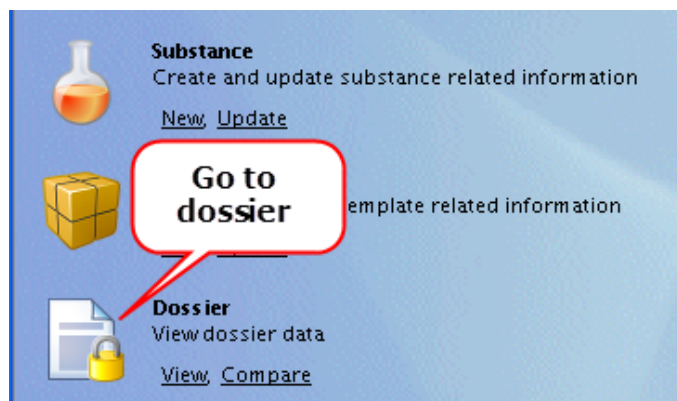
Section number	Section name	Document name	Failure description	Type
Section 13	Assessment Reports		Section 13 is invalid or missing. A CSR or a justification for not providing a CSR must be included. - In order to submit a CSR, one must select 'REACH Chemical safety report (CSR)' in the field 'Type of 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

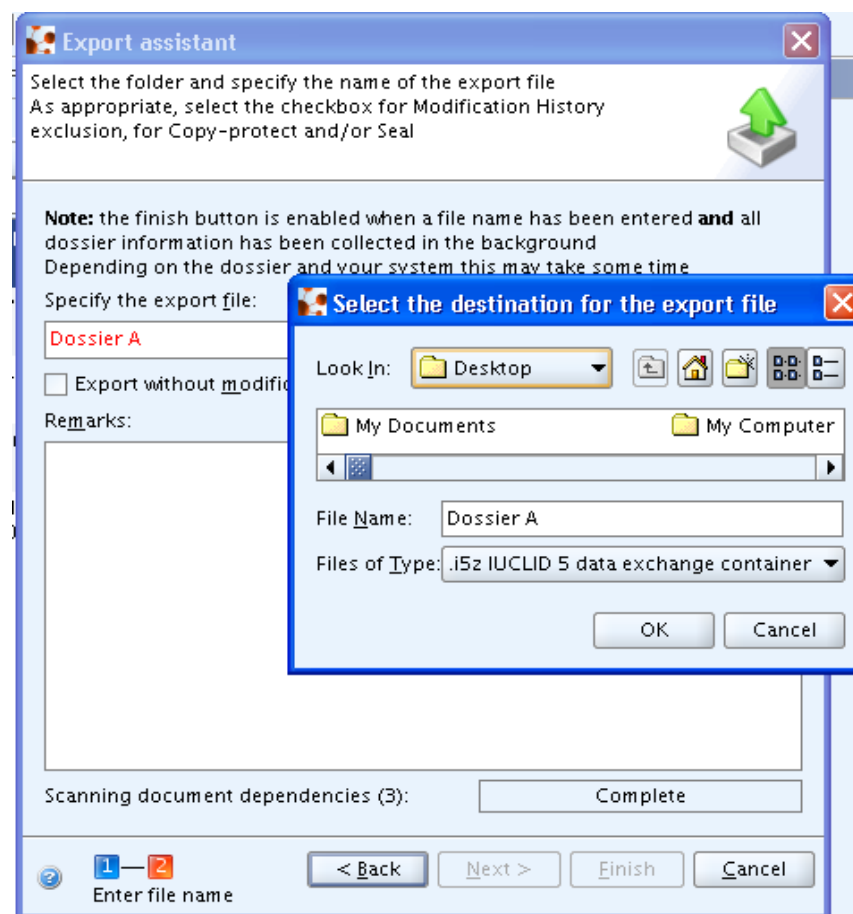
TCC result

< Back Next > Finish Cancel

Export the dossier



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



Thank you

Vasileios TSIFOUTIS

vasileios.tsifoutis@echa.europa.eu