

# IT Tools training

Stakeholders' day, 4 April 2017



# Pre-session information



# The Exercise





## The storyline

You are sitting in your Helsinki office and it is a warm and sunny day outside

The calendar on your wall tells you that it's Monday 31 July 2017

Suddenly your phone rings... It's your boss, telling you that your company has decided to start manufacturing the substance ***Oxytraining sulfate*** in Europe as there seems to be a big market for the substance. Your task is to "deal with REACH"!



## The storyline

Reading up on REACH on the ECHA web site you learn that all new substances need to be registered before placed on the market

After a deeper analysis you learn that you first need to **Inquire** to find other potential registrants of the substance. Apparently you all need to share data and **submit jointly** the registration dossier

In the support section you read that you need to use **IUCLID** for the data files and **REACH-IT** for submitting it to ECHA



## The storyline

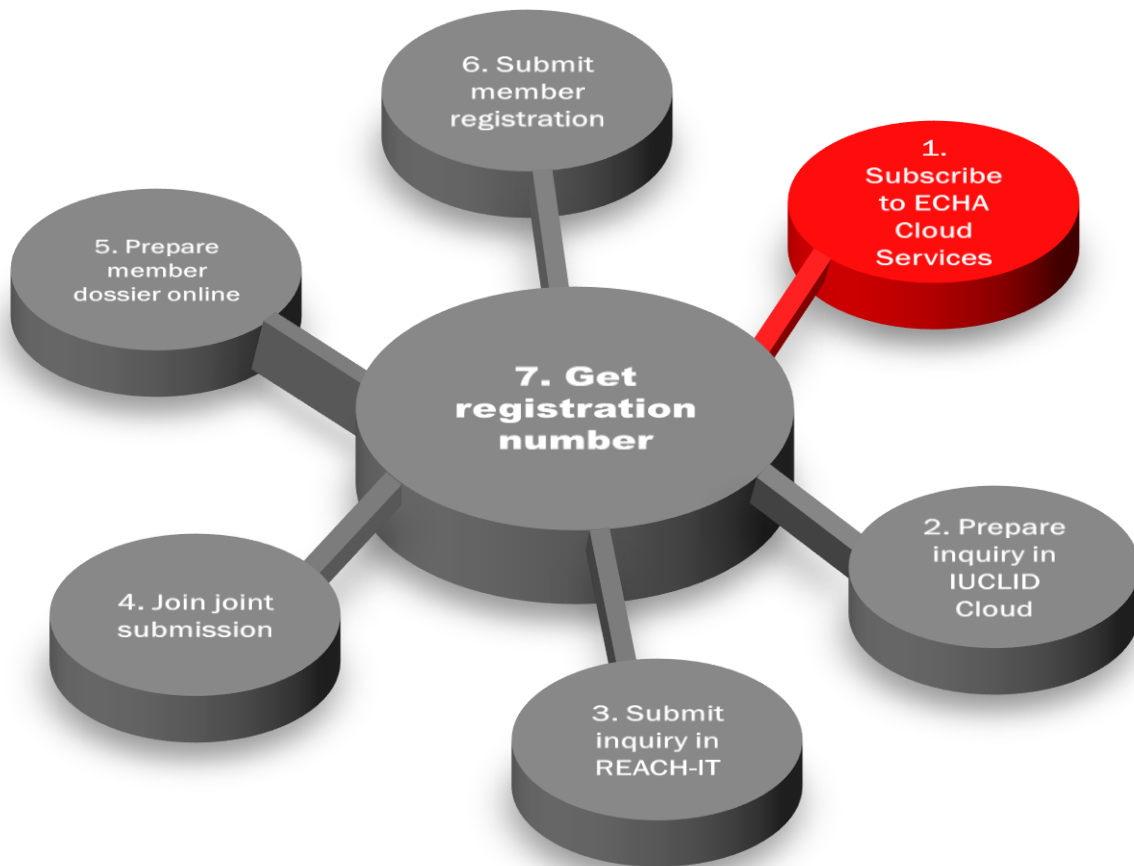
When it comes to IUCLID, you read that you can Download and install it, or as you are an SME you can also use the newly released IUCLID Cloud application from the ECHA Cloud Services.

Apparently you can even create a member registration directly in REACH-IT...

You create an account for the ECHA IT tools and write it down on a piece of paper next to you and get started...

# The goal of the training





1

## Subscribe to ECHA Cloud Services



**ECHA Cloud Services**

Presentation





# **ECHA Cloud Services**



## What is



## ECHA Cloud Services

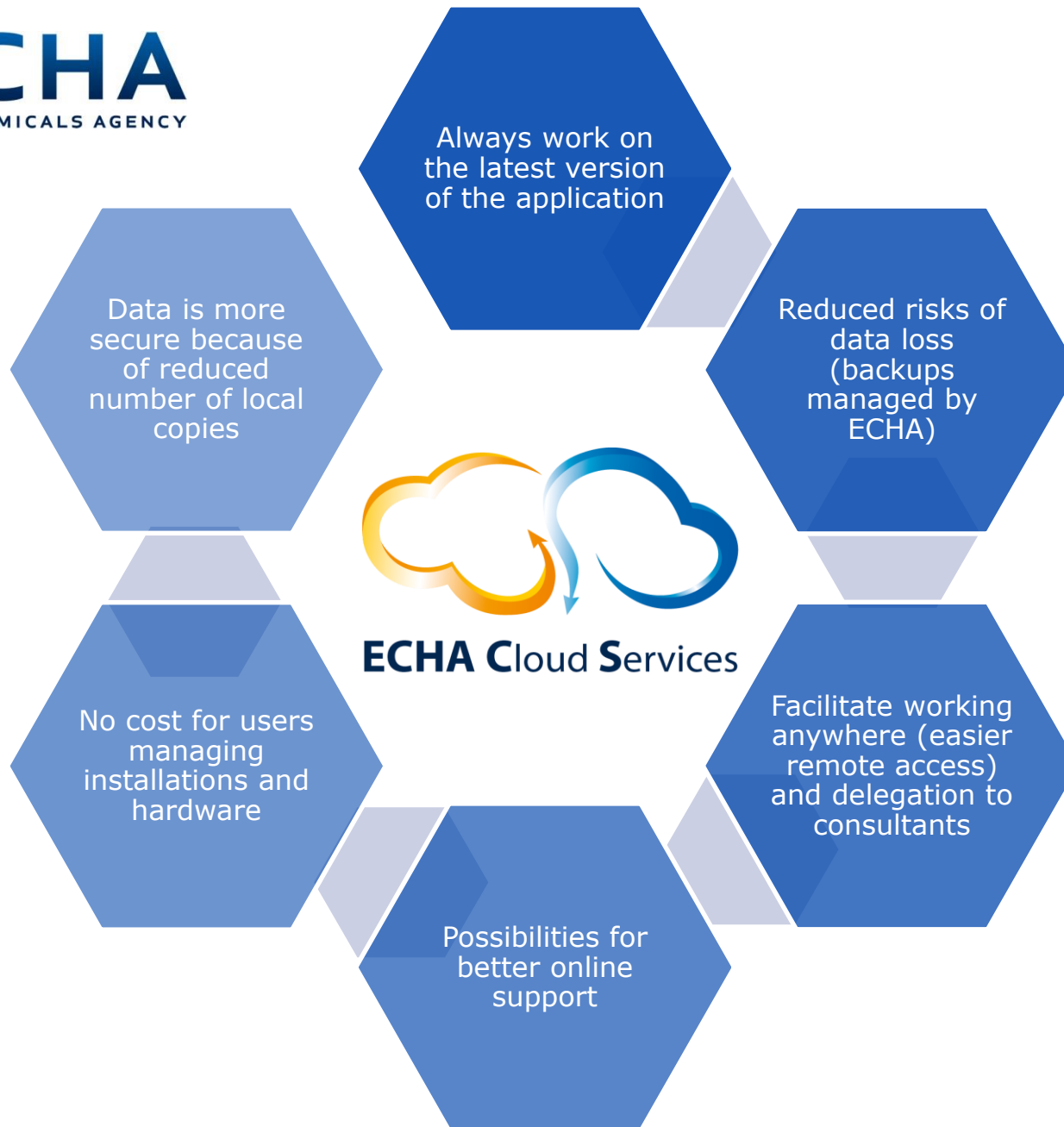
- A new platform for delivery of Business Information systems in ECHA - Released today!
- Triggers
  1. The need to maintain an operational IUCLID version has been raised as a burden for Small and Medium size Enterprises (SMEs)
  2. The usage of IUCLID for non-frequent users is seen as complex
- Solution
  - Provide IUCLID 6 as a Cloud service and simplify the usage for non-frequent users



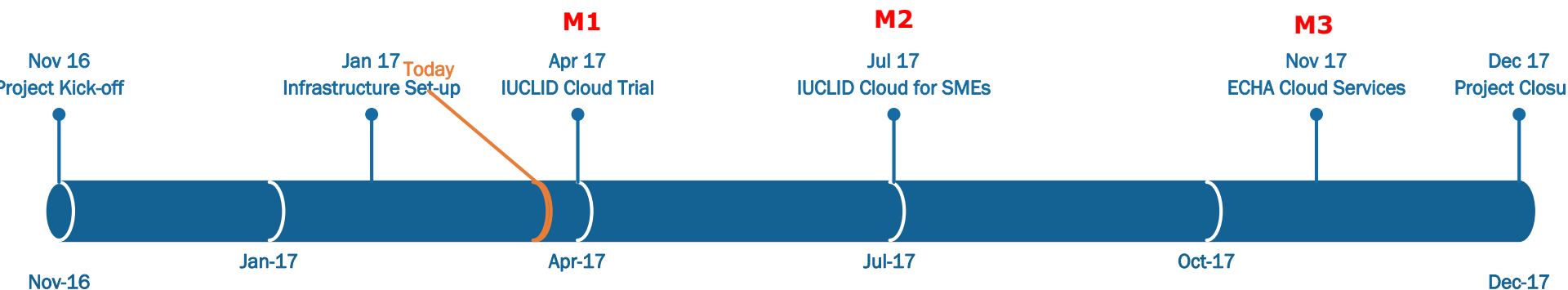
**ECHA Cloud Services**

## What are the goals with

- Release ECHA Cloud Services providing IUCLID access through the cloud with the aim to:
  - Significantly reduce the technical burden and costs (financial, labour) for hosting, updating and managing IUCLID locally for industry
  - Ensure better protection against loss of data and ensure continuous availability of on-line IUCLID services over the internet
- Pave the future of the Business Information Systems delivery

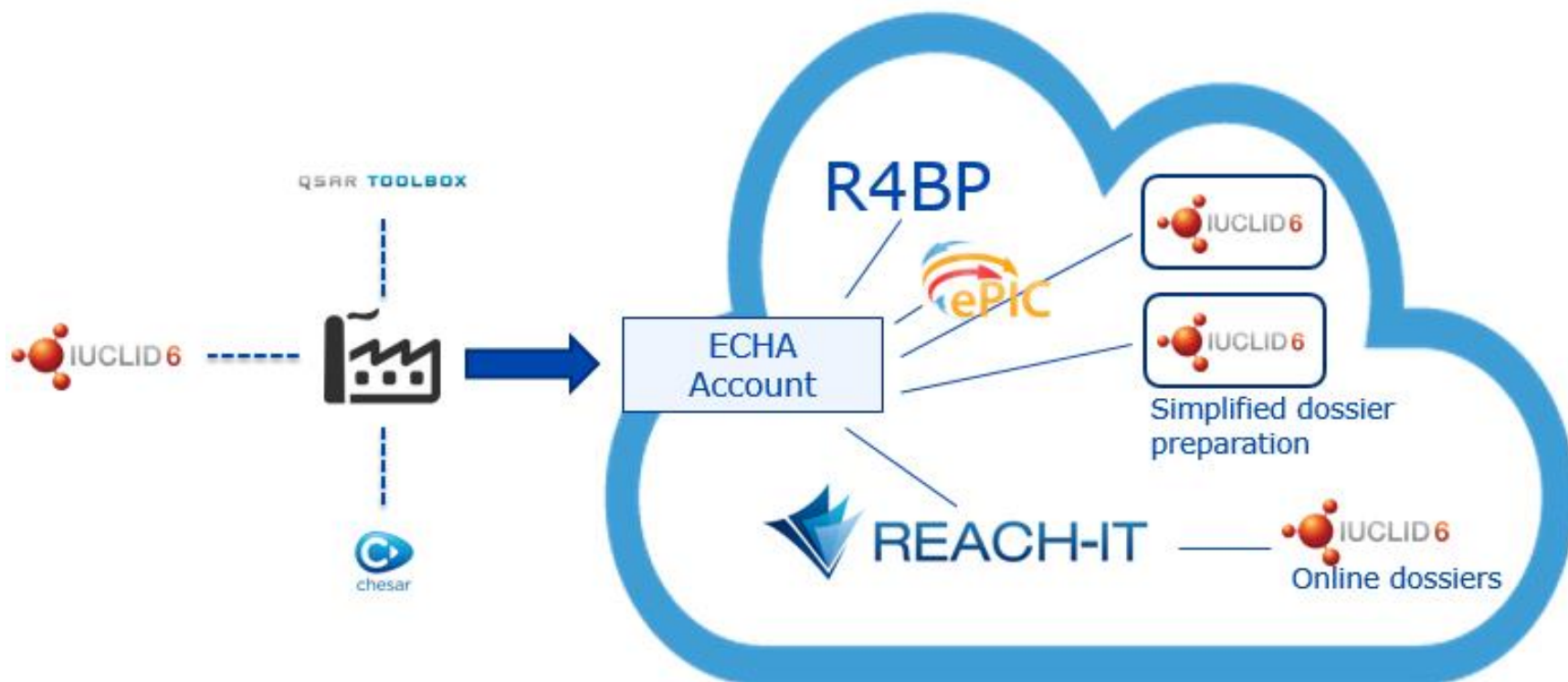


# Milestones



1. IUCLID Cloud trial
  - first access to the service
  - IUCLID data can be browsed with a web interface and edited with the 'IUCLID Cloud client'
2. IUCLID Cloud services for SMEs available (*mid 2017*)
3. Easier dossier preparation with the help of tasks (*end 2017*)

# ECHA Cloud Services



## What service are provided?



IUCLID Cloud Trial (April 2017)



IUCLID Cloud for SMEs (Summer 2017)

## IUCLID Cloud for SMEs



- Aimed for SME users to prepare registration dossiers under REACH for 2018 deadline
- Work fully on a web browser without installing anything locally
- Automated backup and data recovery in case of data loss
- Helpdesk support during office hours
- Immediate subscription activation
- Up to 1 GB of secure data storage
- Target 24/7 availability except for pre-defined maintenance periods occurring outside the working hours
- Controlled service updates with every new release of IUCLID
- Integrated help and support for dossier preparation (End 2017)



# IUCLID Cloud

Support functionalities

The screenshot shows the IUCLID Cloud dashboard. On the left is a navigation menu with items: Dashboard, Substances, Mixture/Products, and Dossiers. The main area contains two panels: 'SUBSTANCES' with a '+ New' button and a flask icon, and 'IMPORT IUCLID FILE' with a 'Drop file to upload' area and a 'Browse' button. A 'Download App' button is at the bottom left. A user profile 'ECS\_Test\_X102' is at the top right.

Creation of new substance

Collapsible navigation menu

Quick access to Substances

Import easily IUCLID Data

Launch the IUCLID Cloud Client for full IUCLID 6 functionality

# IUCLID Cloud

## ECHA Training substance

IUC5-16d020d0-fe12-4b08-9387-9afdf35e588c

### SUBMISSION TYPE

REACH Registration 10 - 100 tonnes

### TABLE OF CONTENTS

- 1. General information\* 3
- 2. Classification & Labelling and PBT assessment\* 4
- 3. Manufacture, use and exposure\* 10
- 4. Physical and chemical properties\* 19
- 5. Environmental fate and pathways\* 20
- 6. Ecotoxicological information\* 17
- 7. Toxicological information\* 24
- 8. Analytical methods 0
- 11. Guidance on safe use\* 0
- 12. Literature search 0
- 13. Assessment reports\* 0
- 14. Information requirements 0

UUID	IUC5-16d020d0-fe12-4b08-9387-9afdf35e588c	Legal entity	ECHA CSR Example
CAS number	11111-11-1	EC number	

- 1 GENERAL INFORMATION\* 3
  - 1.1 Identification 1
    - ECHA Training substance Last Modified 21/03/2017 00:49
  - 1.2 Composition\* 1
    - ECHA Substance Last Modified 21/03/2017 00:49
  - 1.3 Identifiers
  - 1.4 Analytical Information\* 1
    - Analytical Information Last Modified 21/03/2017 00:49
  - 1.5 Joint submission

Shortcuts to all sections

IUCLID Tree view with access to all documents

# IUCLID Cloud

Open the document for editing



ENU

ECHA Substance  
a5804d25-2dda-3e4f-a1b5-333816b90ab3

ECS\_Test\_X102  
ECS Test company 102

Edit in IUCLID app

- DOCUMENT SECTIONS
- General Information
- Classification
- Labelling
- Notes

Shortcuts to sub-sections

Access additional information and attachments

Document easily readable

**General Information**

Name	ECHA Substance
Not classified	false

...tion. The impurities in the ECHA Substance have no hazardous effects and thus do not affect the classification of the ECHA Substance.

Related composition    ✓ ECHA Substance

**Classification**

**Physical Hazards**

**Explosives**

Reason for no classification    conclusive but not sufficient for classification

**Flammable gases and chemically unstable gases**

Reason for no classification    data lacking

**Aerosols**

Reason for no classification    data lacking

**Oxidising gases**

+ About Us

+ Regulations

+ Addressing Chemicals of  
Concern

+ Information on Chemicals

+ Chemicals in our Life

- Support

+ Guidance

+ Getting started

> Q&As Support

> Testing methods and  
alternatives

+ Webinars

- Dossier Submission Tools

> Manuals

+ REACH-IT

> IUCLID

## ECHA Cloud Services

ECHA Cloud Services is a secure online platform used to distribute ECHA's IT applications in a cloud environment.

The first services focus on IUCLID as it is crucial for the 2018 registration deadline. Their functionalities are prioritised for the needs of small and medium-sized enterprises (SMEs). The IUCLID Cloud application runs in a browser and, therefore, complements the IUCLID application in helping SMEs to register their chemicals for the upcoming registration deadline.

To access the cloud space, you need to log in using your ECHA Account credentials. These are the same that you have, for example, to access REACH-IT. If you do not have an ECHA Account, you can create one on the ECHA Cloud Services web page before accessing a service.

Once you are logged in, you can select between the available services:

1. IUCLID Cloud Trial
2. IUCLID Cloud for SMEs

### IUCLID Cloud Trial

Try out the service by working fully on a web browser without installing anything locally. This service gives you 100 MB of data storage and will be automatically updated whenever there is a new release of IUCLID. As this is a trial version, there are no backups taken of the data or dedicated helpdesk support.

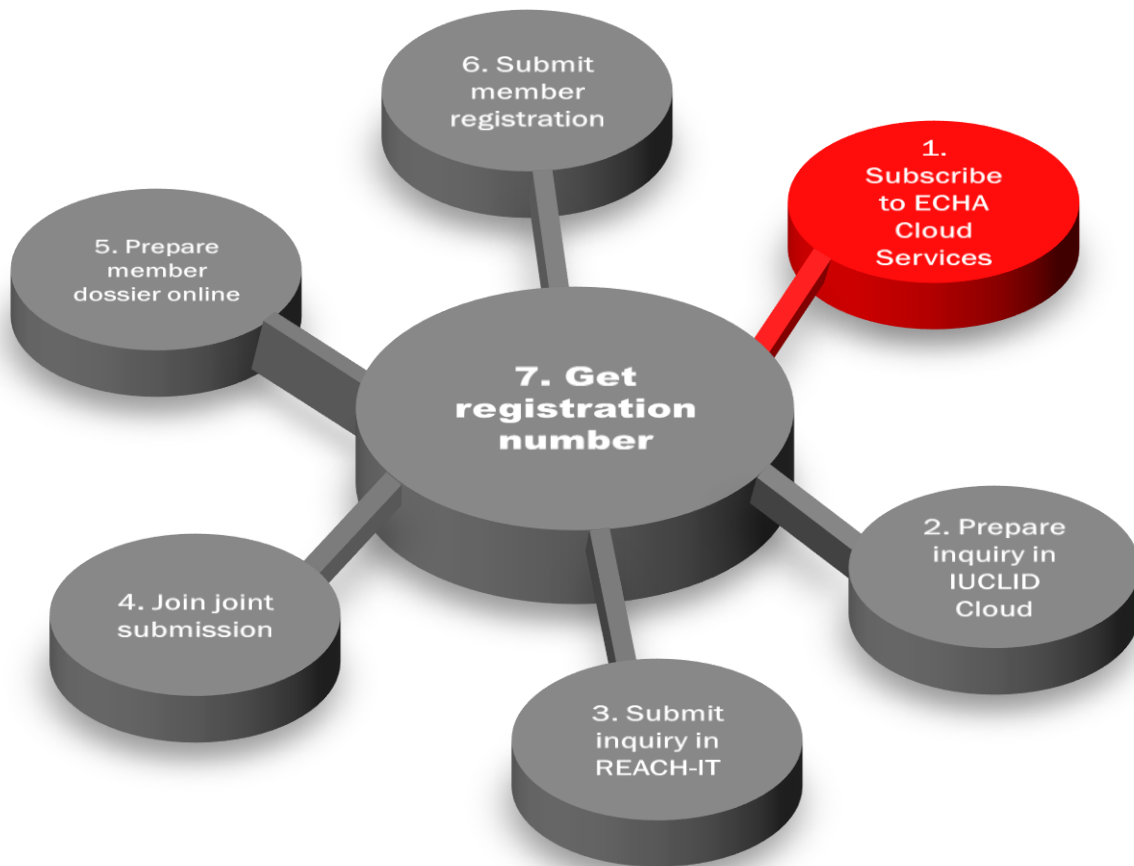
You can either use the IUCLID Cloud application to import and view your substance, mixture and dossier datasets or launch the IUCLID Cloud client (traditional IUCLID that stores data in the cloud) to edit datasets. However, you will not yet be able to use all IUCLID functionalities. These will be available in July 2017 when the IUCLID Cloud for SMEs is launched.

[Access ECHA Cloud Services](#)

### See also

- > [Q&A on ECHA Accounts](#)
- > [What is IUCLID?](#)
- > [IUCLID website](#)
- > [Terms and conditions for using the Cloud Services \[PDF\]](#)
- > [REACH 2018: Prepare your registration as a IUCLID dossier](#)
- > [Simpler IUCLID for smaller companies, Newsletter 4/2016](#)

- A new platform for delivery of Business Information systems, initially used for distributing IUCLID Cloud
- The cloud distribution of IUCLID is a complemented service to the downloadable versions of IUCLID
- Initial aim is to support SMEs users in their preparation for the REACH 2018 deadline – Trial release
- Security is at the heart of the ECHA Cloud Services. Global measures such as encrypted communications between the client computer and the Cloud are enforced
- SMEs can from 04/04/2017 start to get familiar with the IUCLID Cloud Trial, but the main service will be released in summer 2017



1

## Subscribe to ECHA Cloud Services

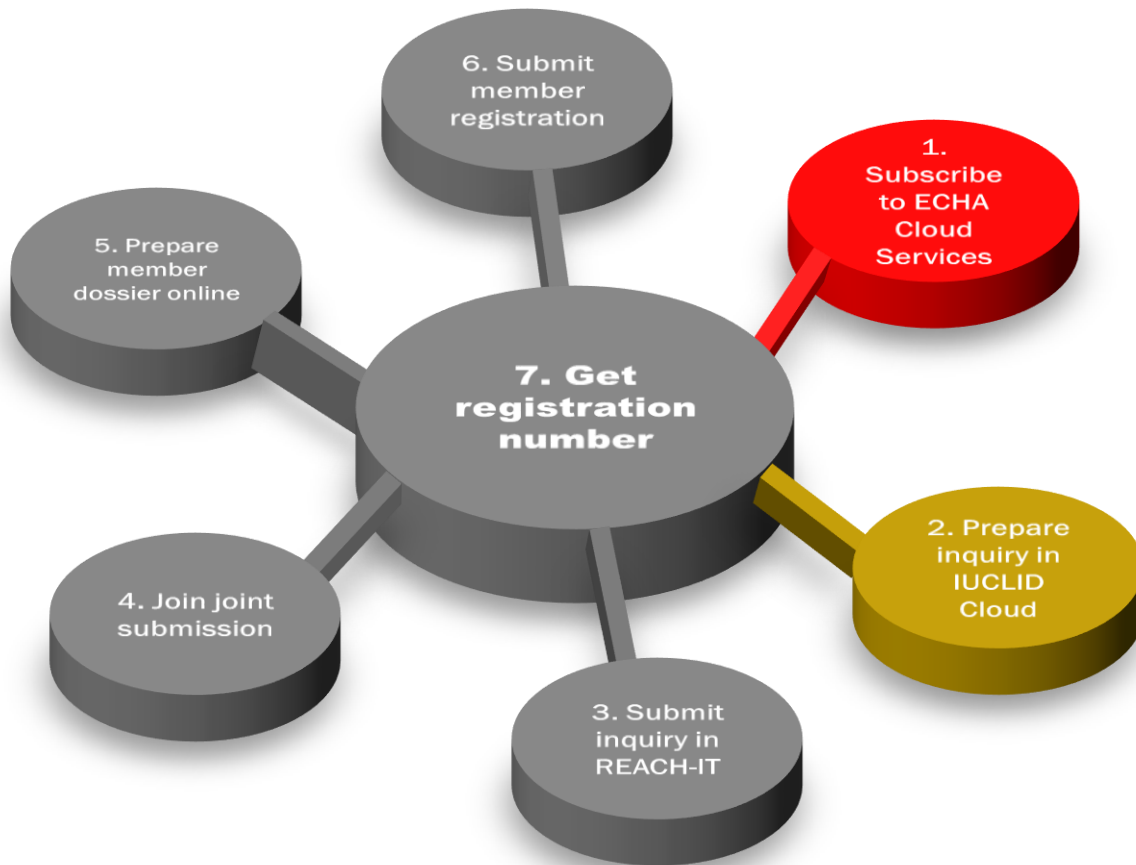


**ECHA Cloud Services**

**Demo subscription**

# IUCLID 6



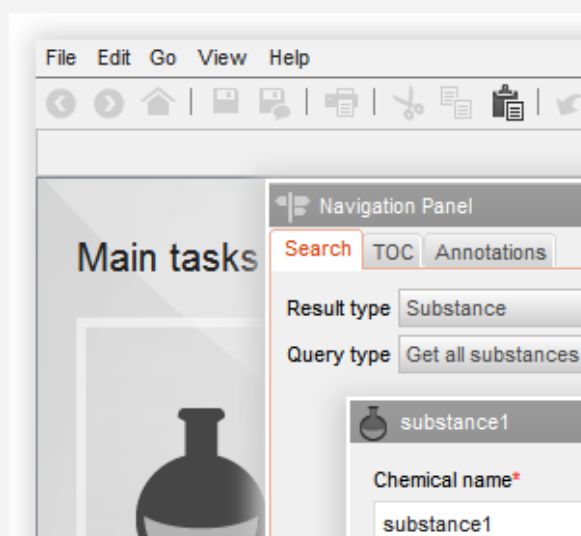


## 2

### Prepare inquiry in IUCLID Cloud

- Introduction on IUCLID 6 and IUCLID 6 main functions
- Exercise





Download

IUCLID 6 plays a central role in the IT environments

29 April 2016

### **IUCLID 6 is available**

A new major version of IUCLID, used for managing scientific information in a regulatory context, is now online. Updated manuals and plugins are also available.

12 April 2016

### **A new IUCLID 6 test version is available**

This test version includes bugs fixes and improvements.

5 February 2016

### **Test a new version of IUCLID 6**

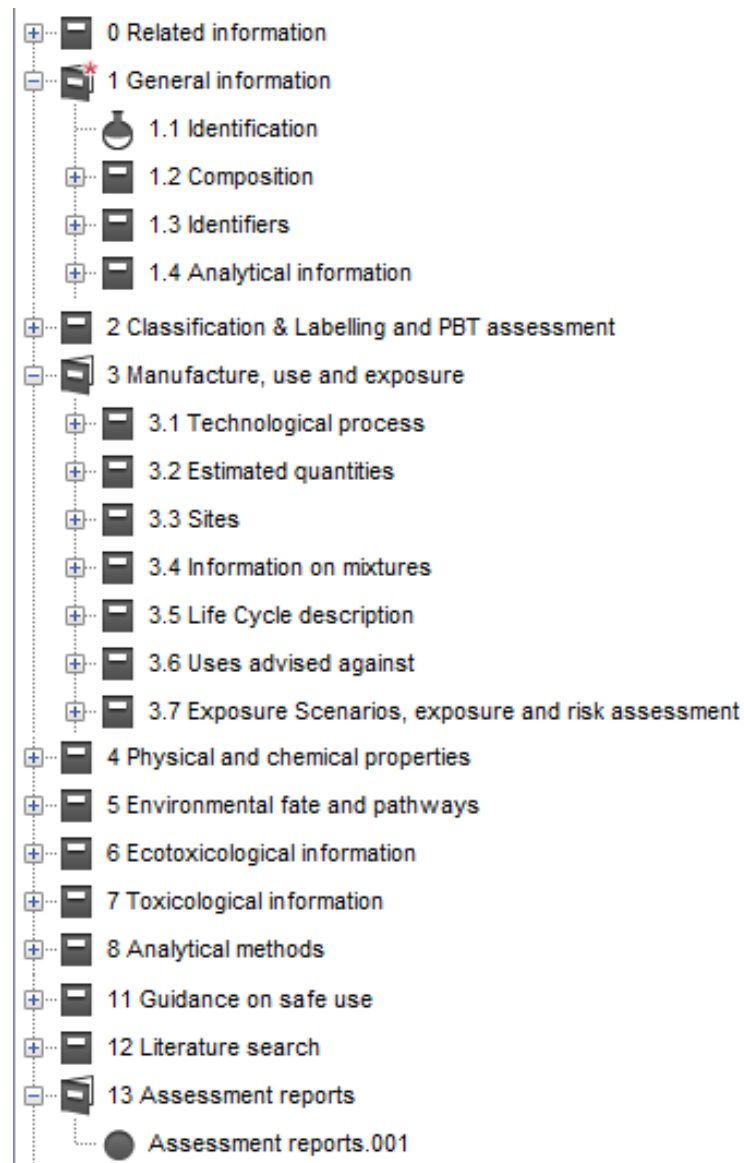
You can now download the latest IUCLID 6 test versions directly from this website.

24 November 2015

### **Register to be part of the IUCLID 6 testing**

IUCLID 6 development continues and new test versions are made available to registered testers.

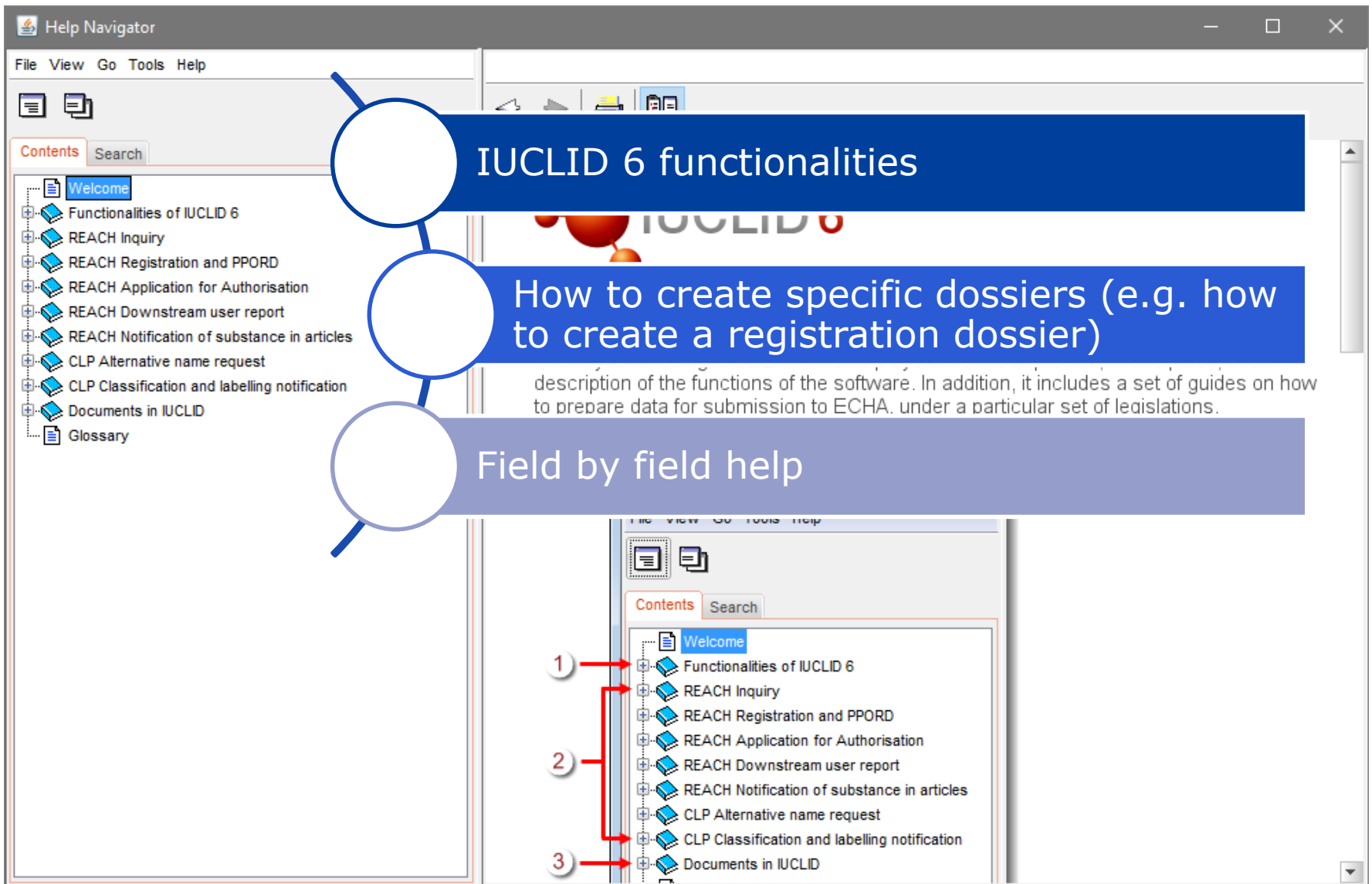
- Section 1:
  - Substance identification
  - Composition(s)
- Section 3: manufacture, use and exposure (CSR sections 9-10 extract - structured fields)
  - Section 3.2 – Estimated quantities
  - Section 3.5 – Life cycle description: brief description of uses based on the REACH use descriptor system
  - Section 3.7 – Exposure scenarios, exposure and risk assessment
- Sections 4 – 7 (OECD Harmonised templates)
- Section 13: assessment reports
  - The CSR document is attached to this section as a Word or PDF file



The screenshot shows the ECHA database interface with several callout boxes:

- Substance:** Create new or modify your existing substances here
- Mixture / Product:** Create a template to reuse same endpoint data in different datasets.
- Template:** View your dossiers
- Dossier:** Search by UUID
- Import:** Import files: LE, substance datasets, reference substances
- Inventory:** Store chemical information on particular chemicals once in the database and link it from there to any IUCLID section.
- Validation assistant:** Validate the substance datasets and also the final dossiers in order to minimize the risk for errors
- Dissemination preview:** View what information will be published on the ECHA website

The interface also includes sections for **Main tasks** (Substance, Mixture / Product, Template, Category, Annotation, Dossier), **Administration** (My account, Import, Bulk export), and **Inventories** (Legal entity, Legal entity site, Reference substance, Contacts, Chemical inventories, Literature reference).



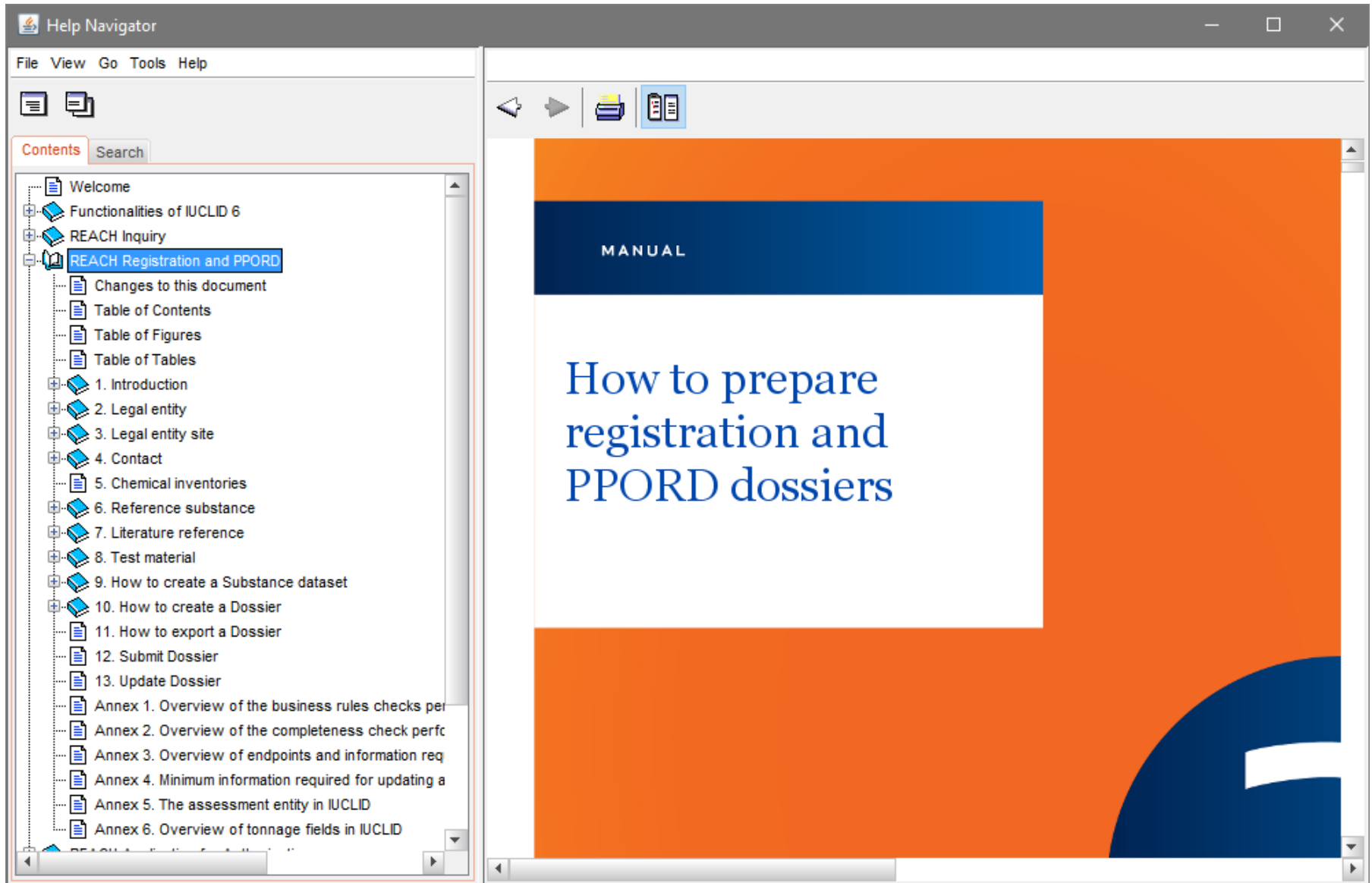
**IUCLID 6 functionalities**

**How to create specific dossiers (e.g. how to create a registration dossier)**

description of the functions of the software. In addition, it includes a set of guides on how to prepare data for submission to ECHA, under a particular set of legislations.

**Field by field help**

- 1
- 2
- 3



The screenshot displays the 'Help Navigator' application window. The left pane shows a hierarchical tree view of the help content. The right pane displays the selected document, which is the manual page titled 'How to prepare registration and PPORD dossiers'.

**Help Navigator**

File View Go Tools Help

Contents Search

- Welcome
- Functionalities of IUCLID 6
- REACH Inquiry
- REACH Registration and PPORD**
  - Changes to this document
  - Table of Contents
  - Table of Figures
  - Table of Tables
  - 1. Introduction
  - 2. Legal entity
  - 3. Legal entity site
  - 4. Contact
  - 5. Chemical inventories
  - 6. Reference substance
  - 7. Literature reference
  - 8. Test material
  - 9. How to create a Substance dataset
  - 10. How to create a Dossier
  - 11. How to export a Dossier
  - 12. Submit Dossier
  - 13. Update Dossier
  - Annex 1. Overview of the business rules checks per
  - Annex 2. Overview of the completeness check perfc
  - Annex 3. Overview of endpoints and information req
  - Annex 4. Minimum information required for updating a
  - Annex 5. The assessment entity in IUCLID
  - Annex 6. Overview of tonnage fields in IUCLID

**MANUAL**

## How to prepare registration and PPORD dossiers

# Creating a complete dossier

1

- Create the dataset
- Fill-in the information

2

- Run the Validation Assistant on the dataset
- Correct the failures

3

- Create the dossier
- Run the Validation Assistant on the dossier
- *In case of failures, correct the dataset or re-create the dossier*

# Creating a complete dossier

1

- **Create the dataset**
- **Fill-in the information**

2

- Run the Validation Assistant on the dataset
- Correct the failures

3

- Create the dossier
- Run the Validation Assistant on the dossier
- *In case of failures, correct the dataset or re-create the dossier*

# Datasets list

IUCLID 6

File Edit User Admin Help

Navigation Panel

Search TOC Annotations

Result type: Substance

Query type: Get all substances

Clear Search

Chemical name	Legal entity name	Reference substance	Last modification date
dewdwed	frefrefef		2016-03-29T11:23:00...
<b>Complete_fullTB</b>	Example Company 1	myrtecaine / 2-[2-(6,6-dimethylbi... / 7712-50-7 / 231-7	2016-01-14T12:02:19...
2014 IUCLID 5 Test Dataset for IUCLID 6 migration	European Chemicals ...	REFERENCE_SUBS... / 50-00-0 / 222-888	2016-03-29T14:07:31...
Member_1	Example Company 1	labetalol / 2-hydroxy-5-(1-hyc... / 36894-69-6 / 253-	2016-01-14T15:34:00...

Complete\_fullTB1 / myrtecaine / 2-[2-(6,6-dimethylbicyclo[3.1.1]hept-2-en-2-yl)ethoxy]-N,N-diethylethanamine / 7712-50-7

Substance name\*

Complete\_fullTB1

Public name

Test

Legal entity flags

Legal entity\*

Example Company 1 / Example city / Finland

Third party flags

Third party

Role in the supply chain ^

Role flags

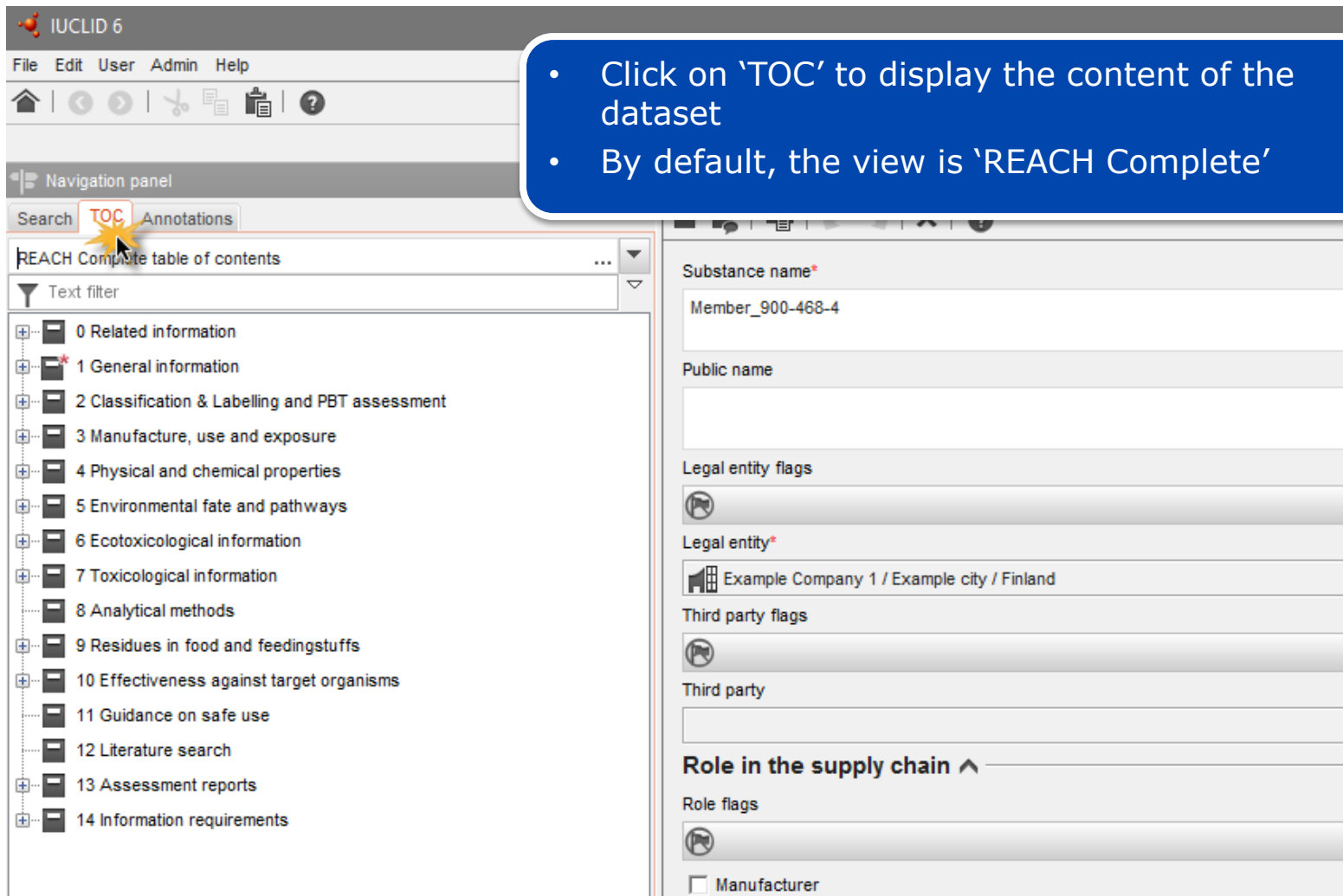
Manufacturer

Importer

Only representative



# Dataset content



- Click on 'TOC' to display the content of the dataset
- By default, the view is 'REACH Complete'

Substance name\*

Member\_900-468-4

Public name

Legal entity flags

Legal entity\*

Example Company 1 / Example city / Finland

Third party flags

Third party

Role in the supply chain ^

Role flags

Manufacturer

# Adapting view to submission types

The screenshot shows the IUCLID 6 software interface. A blue callout box contains the text: "Adapt the view according to your needs (e.g. preparation of a registration dossier as a member of a joint submission)". The main interface includes a menu bar (File, Edit, User, Admin, Help), a navigation panel with tabs for Search, TOC, and Annotations, and a table of contents. A 'Pick list' dialog box is open, displaying a list of submission types. The selected option is "REACH Registration member of a joint submission - general case".

Adapt the view according to your needs (e.g. preparation of a registration dossier as a member of a joint submission)

Pick list

Select a value

- 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

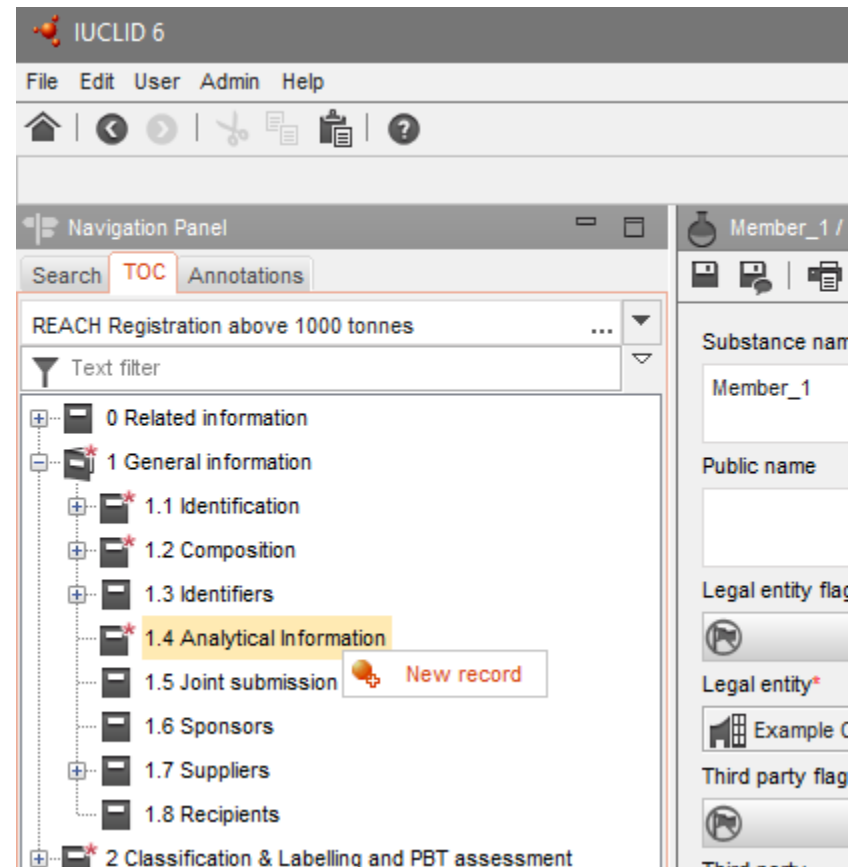
## Filling-in a dataset: mandatory sections

- Mandatory sections are indicated with a red mark: \*
- This is only an indication and the Validation Assistant should be run to verify the completeness of a dossier

The screenshot displays the IUCLID 6 software interface. The main window shows a tree view of a dossier structure for 'REACH Registration above 1000 tonnes'. The 'General information' section (1) is highlighted in yellow and contains sub-sections 1.1 through 1.8. Many of these sub-sections (1.1, 1.2, 1.4, 1.7, 1.8) and other higher-level sections (2, 3, 4, 5, 6, 7, 11, 13, 14) are marked with a red asterisk (\*), indicating they are mandatory. The right-hand side of the interface shows a form for 'Complete\_fullTB1 / myrtecain', with fields for 'Substance name\*', 'Public name', 'Legal entity flags', 'Legal entity\*', 'Third party flags', 'Third party', and 'Role in the supply chain'. The 'Role flags' section includes checkboxes for 'Manufacturer', 'Importer' (checked), and 'Only representative'.

## Filling-in a dataset: creating records

- Right-click on a section to create a new record
- Fill-in the information



# Creating a complete dossier

1

- Create the dataset
- Fill-in the information

2

- **Run the Validation Assistant on the dataset**
- **Correct the failures**

3

- Create the dossier
- Run the Validation Assistant on the dossier
- *In case of failures, correct the dataset or re-create the dossier*

## Validation assistant

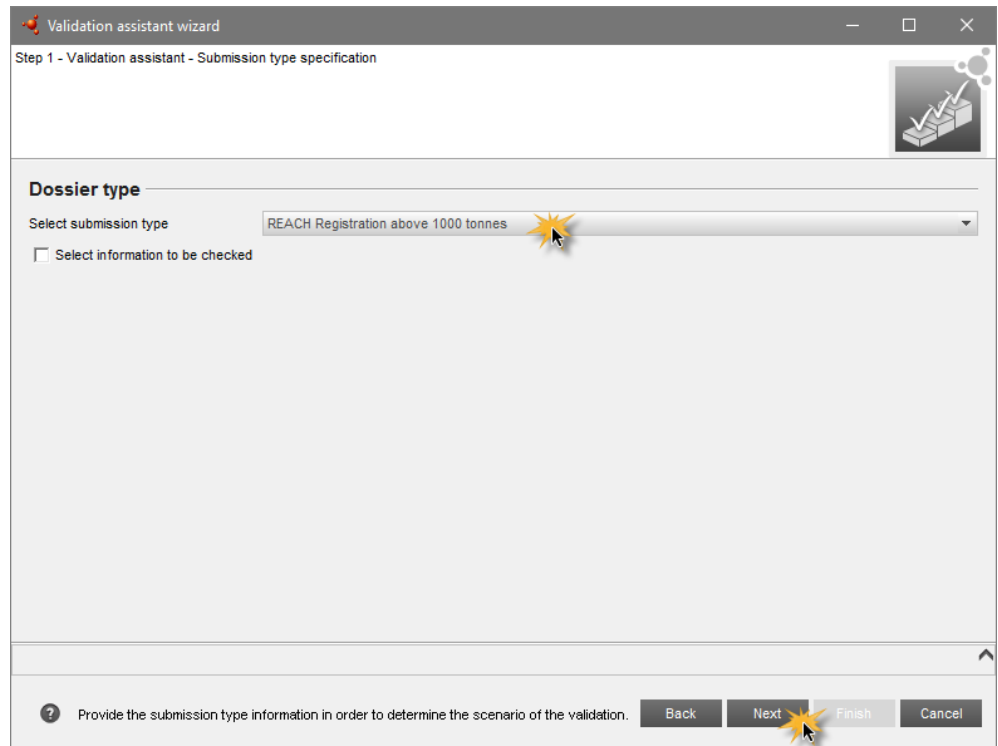
- Access the substance datasets
- Right-click on the dataset and select Validate

The screenshot shows the IUCLID 6 application window. At the top right, a blue arrow with the number '2' points to the interface. The main window has a menu bar (File, Edit, User, Admin, Help) and a toolbar. Below is a 'Navigation Panel' with search filters. The 'Result type' is set to 'Substance' and the 'Query type' is 'Get all substances'. A 'Search' button is visible. Below the search area is a table with columns: Chemical name, Legal entity name, Reference substance, and Last modification date. The table contains several rows, with the row 'Complete\_fullTB1' highlighted in yellow. A context menu is open over this row, listing options: Open, Create Dossier..., Print..., Generate report..., Export..., Delete, and Validate. A mouse cursor is pointing at the 'Validate' option. The 'Validate' option is highlighted with a red checkmark icon.

Chemical name	Legal entity name	Reference substance	Last modification date
dewdwed	frefref		2016-03-29T11:23:00...
Complete_fullTB1	Example Compaov 1	myrtecaine / 2-[2-(6,6-dimethylbi / 7712-50-7 / 231-7	2016-01-14T12:02:19...
2014 IUCLID 5 Test Dataset for IUCLID 6 migratic		REFERENCE_SUBS REFERENCE_SUBS	2016-03-29T14:07:31...
Member_1		labetalol / 2-hydroxy-5-(1-hyc / 36894-69-6 / 253-	2016-01-14T15:34:00...

## Validation assistant

- Access the substance dataset
- Right-click on the dataset and select Validate
- Select the submission type



The screenshot shows a software window titled "Validation assistant wizard" with the subtitle "Step 1 - Validation assistant - Submission type specification". The window contains a "Dossier type" section with a dropdown menu set to "REACH Registration above 1000 tonnes". Below the dropdown is a checkbox labeled "Select information to be checked" which is currently unchecked. At the bottom of the window, there is a status bar with a question mark icon and the text "Provide the submission type information in order to determine the scenario of the validation." followed by four buttons: "Back", "Next", "Finish", and "Cancel". The "Next" button is highlighted with a yellow starburst icon.

## Validation assistant

- Access the substance datasets
- Right-click on the dataset and select Validate
- Select the submission type
- Provide the dossier header information

The screenshot shows a software window titled "Validation assistant wizard" with the subtitle "Step 3 - Validation assistant - Enter additional information concerning your dossier". The window contains several sections for data entry:

- Type of submission:** Includes a checkbox for "Joint submission".
- Tonnage band(s) of the registrant:** Contains two dropdown menus: "On-site isolated intermediates tonnage band (REACH Article 17)" and "Transported isolated intermediates tonnage band (REACH Article 18)".
- Specific submissions:** Includes a checkbox for "The submission is an update".
- Dossier specific information:** Includes a dropdown menu for "Phase-in" (currently set to "phase-in"), a checkbox for "Reviewed by an assessor", and a text field for "Remarks".

At the bottom of the window, there is a status bar with a question mark icon and the text "Submission type header information". On the right side, there are four buttons: "Back", "Next", "Finish", and "Cancel". A mouse cursor is pointing at the "Next" button.



# Validation assistant results

- Total number of failures
- Rule number
- Relevant section
- Document name
- Error message

Validation assistant wizard

Validated entity: Complete\_fullTB1 / myrtecaine / 2-[2-(6,6-dimethylbicyclo[3.1.1]hept-2-en-2-yl)ethoxy]-N,N-diethylethanamine / 7712-50-7  
 Time of validation: 2016/03/30 10:29:40  
 Validation scenario: SC0144 - Registration, lead >1000, own 10-100/100-1000/>1000, CSR, own GSU

Submission checks (2) ! Quality checks (0)

"Business rules (1)", "Completeness check rules (1)"

Re-check Open document Open document Filter: All Rules' outcome: All

Rule	Section nu...	Section name	Document n...	Message	Rule type	Rule level
BR177				Joint submission lead registrants must include at least one composition which describes the collectively agreed boundaries of the registered substance. To this end, indicate in section 1.2 the 'Type of composition' as 'boundary composition of the substance'. Multiple boundary compositions can be provided, if relevant.	Business rule	Failure
TCC_ESR_19	6.1.2	Long-term toxicity to fish	Testing proposal	'Administrative data' is not complete. You have indicated the endpoint study record to be a testing proposal by selecting 'experimental study planned' or 'experimental study planned (based on read-across)' in the field 'Type of information'. A testing proposal on vertebrate animals must document the considerations for why the adaptation possibilities provided by the REACH Regulation cannot be used to address the information requirement. The information must be provided in the field 'Justification for type of information' and will be published on the ECHA website. You are advised to use the text template available for the field to ensure that all the relevant information has been provided.	Completeness check	Failure

Validation assistant - Report Back Next Finish Cancel

# Validation assistant results

- Right-click on a failure to access the incomplete document

Validation assistant wizard

Validated entity: Complete\_fullTB1 / myrtecaine / 2-[2-(6,6-dimethylbicyclo[3.1.1]hept-2-en-2-yl)ethoxy]-N,N-diethylethanamine / 7712-50-7  
 Time of validation: 2016/03/30 10:29:40  
 Validation scenario: SC0144 - Registration, lead >1000, own 10-100/100-1000/>1000, CSR, own GSU

Submission checks (2) ! Quality checks (0)

"Business rules (1)", "Completeness check rules (1)"

Re-check Open document Open document Filter: All Rules' outcome: All

Rule	Section nu...	Section name	Document n...	Message	Rule type	Rule level
BR177				Joint submission lead registrants must include at least one composition which describes the collectively agreed boundaries of the registered substance. To this end, indicate in section 1.2 the 'Type of composition' as 'boundary composition of the substance'. Multiple boundary compositions can be provided, if relevant.	Business rule	Failure
TCC_ESR_19	6.1.2	Long-term toxicity to fish	Testing proposal	'Administrative data' is not complete. You have indicated the endpoint study record to be a testing proposal by selecting 'experimental study planned' or 'experimental study planned (based on read-across)' in the field 'Type of information'. A testing proposal on vertebrate animals must document the considerations for why the adaptation possibilities provided by the REACH Regulation cannot be used to address the information required. The information provided in the field 'Justification for relevant information' must be provided on the ECHA website. You are advised to provide relevant information in the field 'Justification for relevant information'.	Completeness check	Failure

Go to reference document

Go to reference document

Validation assistant - Report

Back Next Finish Cancel

OECD / Long-term toxicity to fish / Testing proposal / Complete\_fullTB1 / myrtecaine / 2-[2-(6,6-dimethylbicyclo[3.1.1]hept-2-en-2-yl)ethoxy]-N,N-diethylet... OECD

**Administrative data** ^

fish early-life stage toxicity ... Remarks ...

Type of information  
experimental study planned ... Other ... Remarks ...

Adequacy of study ...

Robust study summary  
 Used for classification  
 Used for SDS

Study period  
8 months ...

Reliability ... Other ...

Rationale for reliability incl. deficiencies ... Other ... Remarks ...

Data waiving ...

Justification for data waiving

Information Panel

Information Clipboard manager Attachments Modification history Annotations

Type  Endpoint Study Record

UUID IUC5-7f7accf0-2eb8-4a51-931a-54770f050239

Dossier UUID

SuperUser

The incomplete document is displayed

You can (un-)hide the Validation Assistant using this icon

# Refresh the validation assistant results after correcting issues and saving

Validation assistant wizard

Validated entity: Member\_900-467-9 / Paratrainingol\_substance\_iupac  
 Time of validation: 2016/05/23 17:12:47  
 Validation scenario: SC0031 - Registration, member 10-100, own CSR, own GSU

Submission checks (6) ! Quality checks (0)

Business rules (1), Completeness check rules (5)

Re-check Open document Open document Copy report Copy selected row(s) to clipboard Filter: All Rule level: All

Rule	Section number	Section name	Document name	Message	Rule type	Rule level
BR164	2.3	PBT assessment		In section 2.3 - 'PBT assessment', a summary document must be created, and a selection must be made in the field 'PBT status'. If the option 'PBT assessment does not apply' is selected, an explanation must be provided in the field 'Justification'. If several PBT summaries are provided, the 'Assessed composition(s)' must be indicated.  Summary documents are identified with the sigma sign.	Business rule	Failure
TCC_0102_08	1.2	Composition, (1)	Composition.001	For each impurity of a legal entity composition, the full 'Concentration range' must be provided (lower and upper value), together with a unit.  If declaring the absence of a specific impurity, link the appropriate reference substance and indicate the value "0", together with the unit, in the field 'Typical concentration'. Leave the 'Concentration range' fields empty.	Completeness check	Failure
TCC_0104_02	1.4	Analytical Information, (2)	Analytical information.001	The 'Analytical information' provided in section 1.4 is incomplete. At least one row must be created in the table 'Analytical determination'. In each row, the following must be provided: - a selection must be made in the 'Purpose of analysis' picklist - at least one selection must be made in the 'Analysis type' picklist - either an attachment must exist in the 'Attached methods/results' field, or a reason for not providing a method/result must be indicated. To this end, make a selection in the field 'Rationale for no results' and insert an explanation in the	Completeness check	Failure

Validation assistant - Report

Back Next Finish Cancel

# Creating a complete dossier

1

- Create the dataset
- Fill-in the information

2

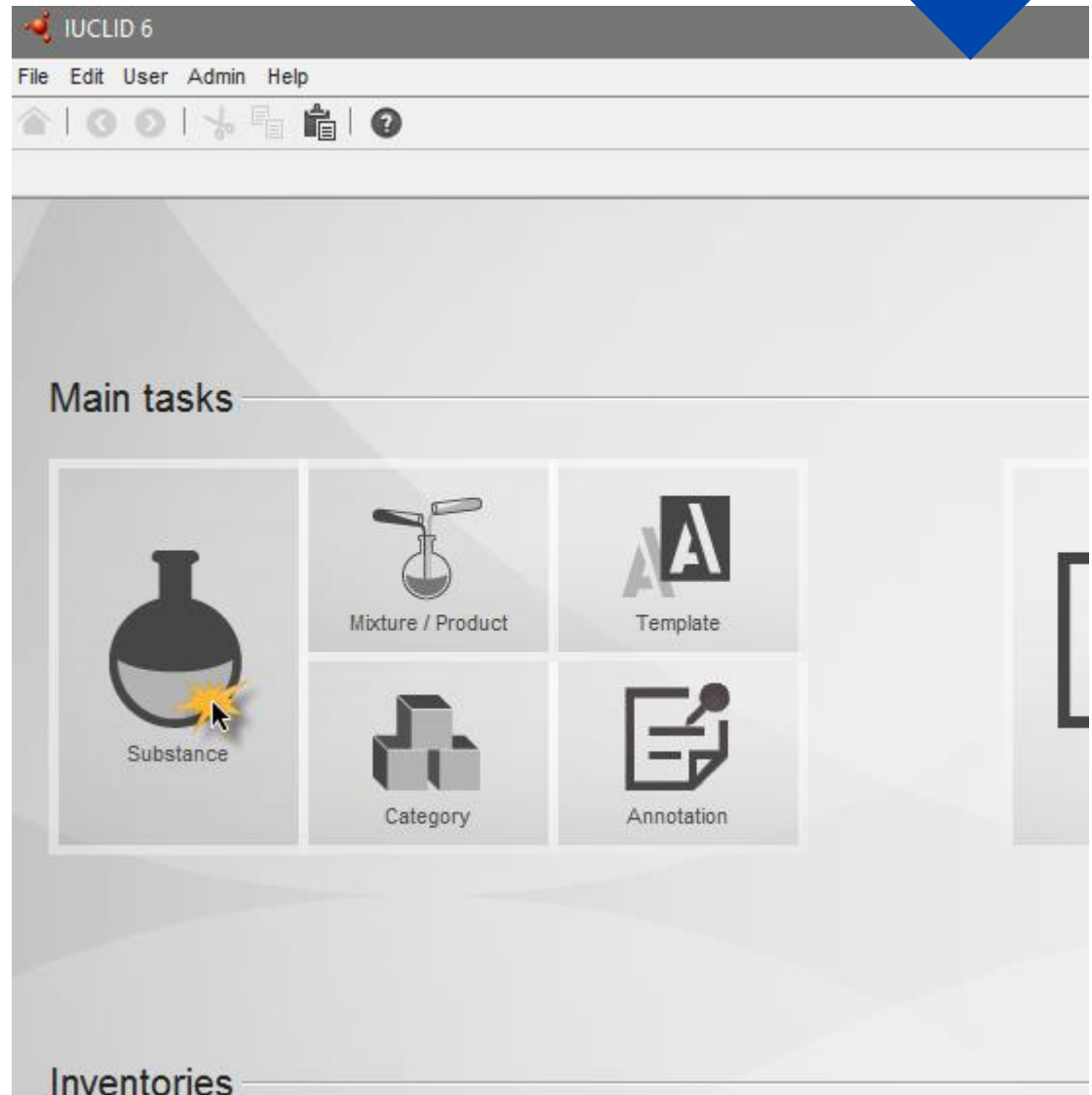
- Run the Validation Assistant on the dataset
- Correct the failures

3

- **Create the dossier**
- **Run the Validation Assistant on the dossier**
- ***In case of failures, correct the dataset or re-create the dossier***

## Dossier creation

- Access your substance datasets



## Dossier creation

- Select the dataset for which you want to create a dossier
- Right-click and create dossier

The screenshot shows the IUCLID 6 software interface. At the top, there is a menu bar with 'File', 'Edit', 'User', 'Admin', and 'Help'. Below the menu bar is a navigation panel with a search bar. The search results are displayed in a table with the following columns: Chemical name, Legal entity name, Reference substance, and Last modification date. A context menu is open over the 'Create Dossier' option in the table.

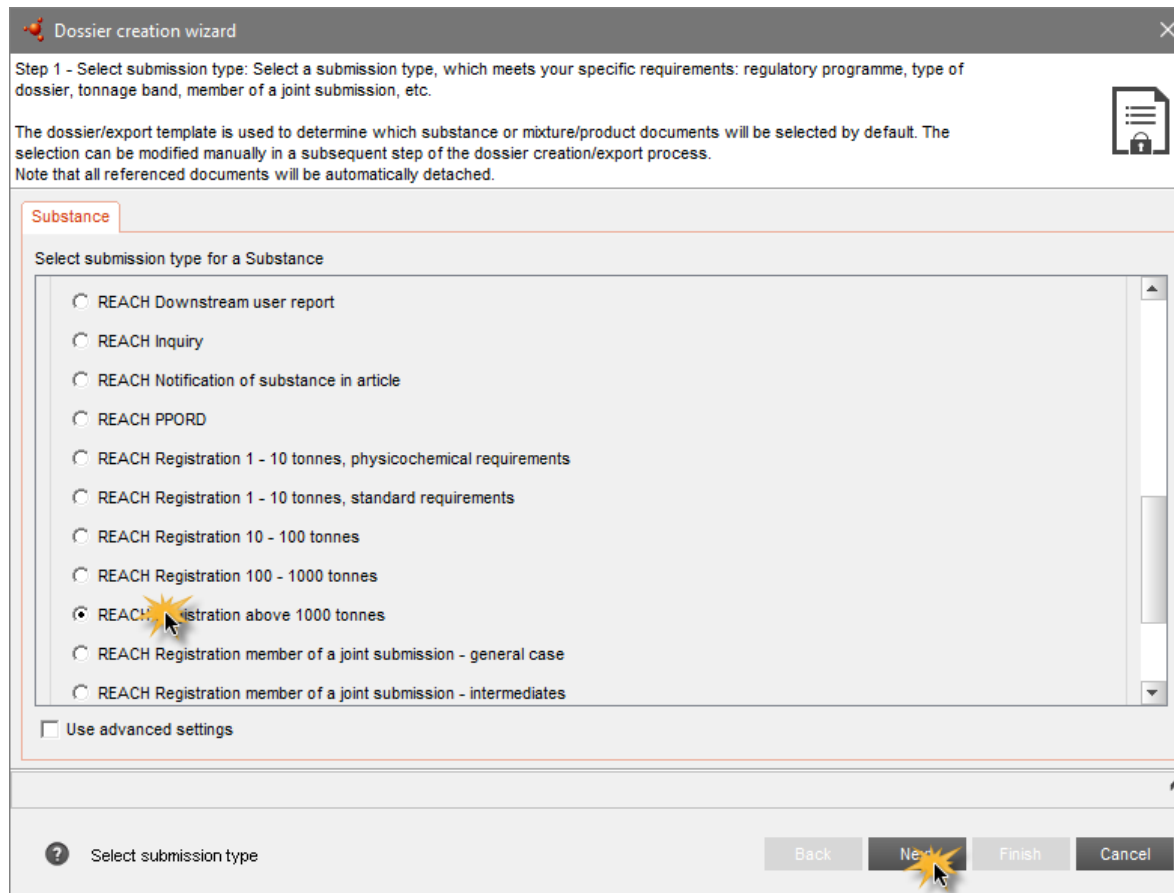
Chemical name	Legal entity name	Reference substance	Last modification date
dewdwd	frefrefef		2016-03-29T11:23:00...
Complete_fullTR1	Example Company 1	myrtecaine / 2-[2-(6,6-dimethylbi / 7712-50-7 / 231-7	2016-01-14T12:02:19...
2014 IUCLID 5 Test Dataset IUCLID 6 migr		REFERENCE_SUBS REFERENCE_SUBS / 50-00-0 / 222-888	2016-03-29T14:07:31...
Member_1		labetalol / 2-hydroxy-5-{1-hyc / 36894-69-6 / 253-	2016-01-14T15:34:00...

The context menu is open over the 'Create Dossier' option, which is highlighted in red. Other options in the menu include 'Open', 'Print...', 'Generate report...', 'Export...', 'Delete', and 'Validate...'.



# Dossier creation wizard

- Select the dossier type



Dossier creation wizard

Step 1 - Select submission type: Select a submission type, which meets your specific requirements: regulatory programme, type of dossier, tonnage band, member of a joint submission, etc.

The dossier/export template is used to determine which substance or mixture/product documents will be selected by default. The selection can be modified manually in a subsequent step of the dossier creation/export process. Note that all referenced documents will be automatically detached.

**Substance**

Select submission type for a Substance

- 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 above 1000 tonnes
- REACH Registration member of a joint submission - general case
- REACH Registration member of a joint submission - intermediates

Use advanced settings

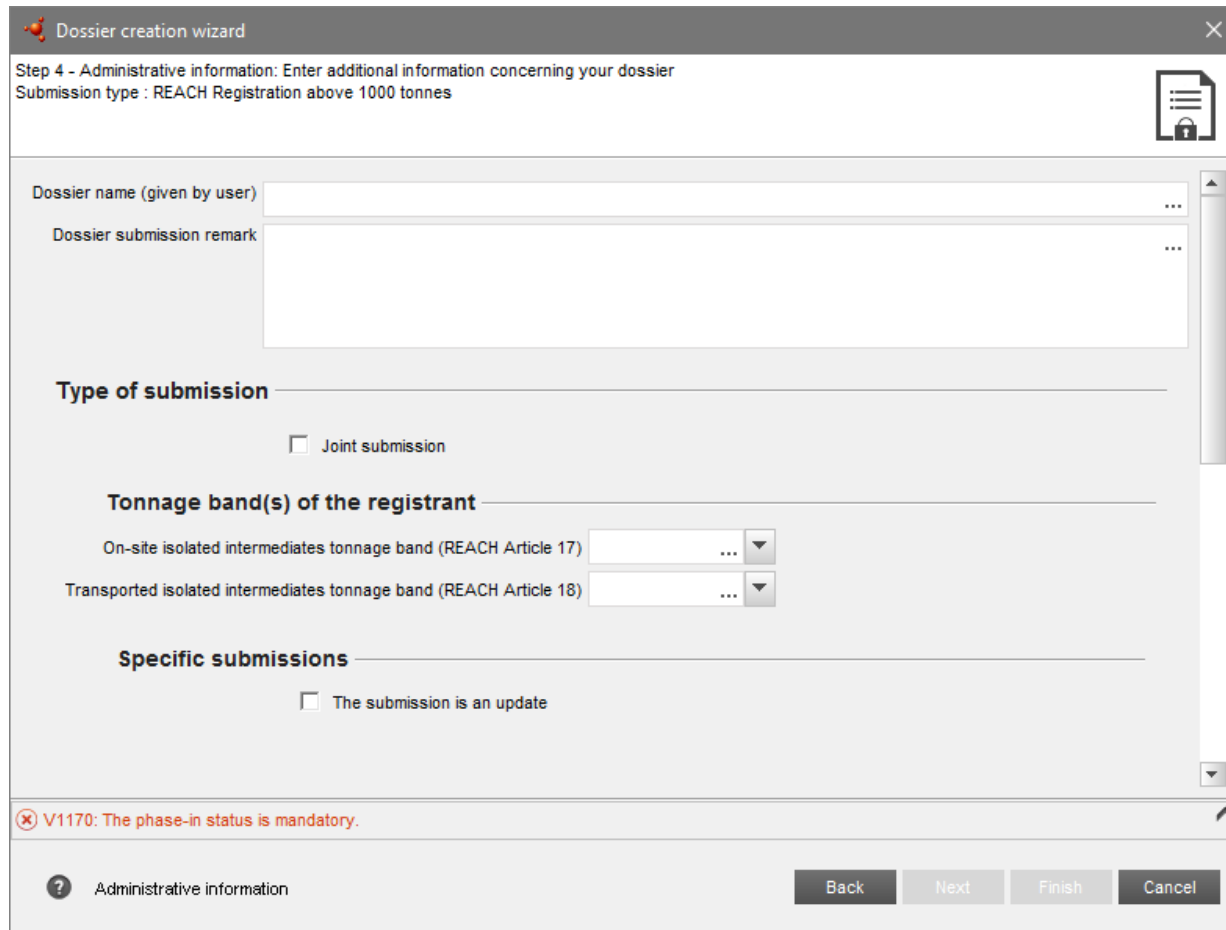
? Select submission type

Back Next Finish Cancel



# Dossier creation wizard

- Fill-in the dossier header



The screenshot shows a software window titled "Dossier creation wizard" with a close button (X) in the top right corner. The window content is as follows:

- Step 4 - Administrative information: Enter additional information concerning your dossier**
- Submission type : REACH Registration above 1000 tonnes
- Icon of a document with a lock symbol.
- Form fields:
  - Dossier name (given by user) [text input] ...
  - Dossier submission remark [text input] ...
- Type of submission**
  - Joint submission
- Tonnage band(s) of the registrant**
  - On-site isolated intermediates tonnage band (REACH Article 17) [dropdown menu] ...
  - Transported isolated intermediates tonnage band (REACH Article 18) [dropdown menu] ...
- Specific submissions**
  - The submission is an update
- Warning message: ✘ V1170: The phase-in status is mandatory.
- Progress indicator: ? Administrative information
- Navigation buttons: Back, Next, Finish, Cancel

# Creating a complete dossier

1

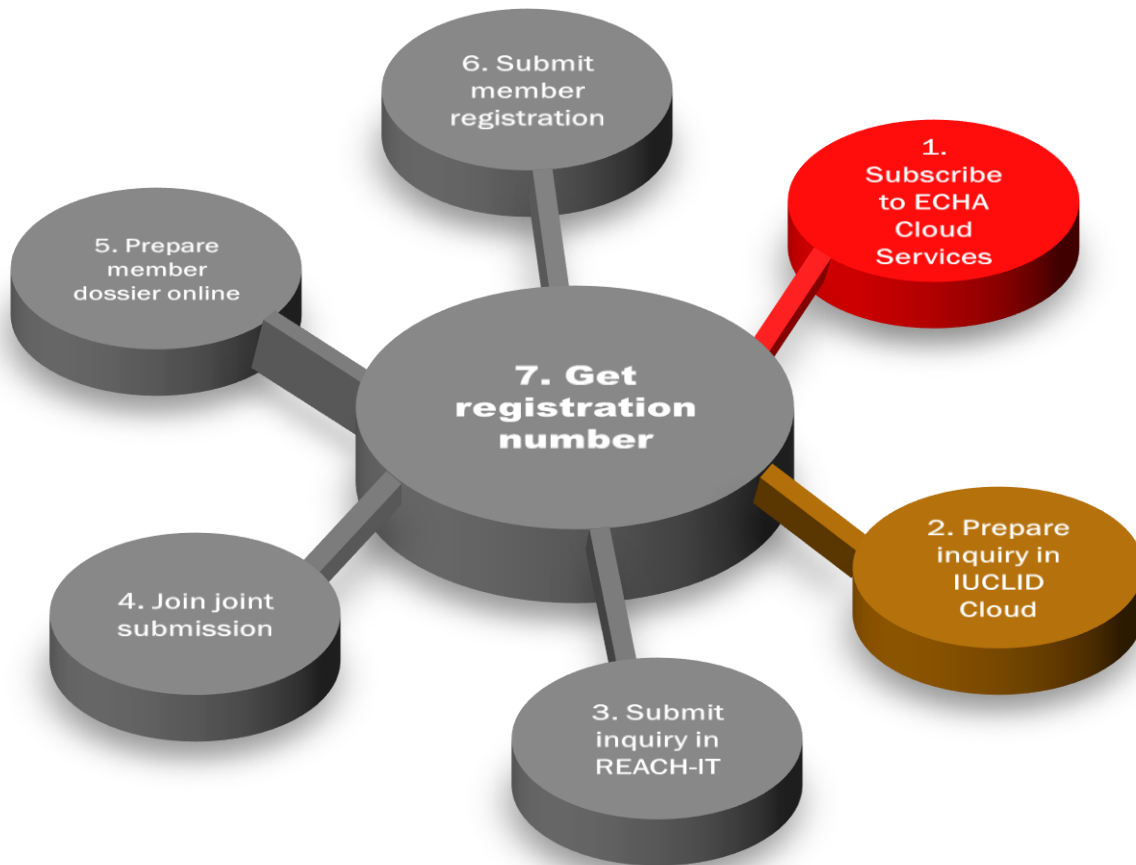
- Create the dataset
- Fill-in the information

2

- Run the Validation Assistant on the dataset
- Correct the failures

3

- Create the dossier
- Run the Validation Assistant on the dossier
- *In case of failures, correct the dataset or re-create the dossier*



## 2

### Prepare inquiry in IUCLID Cloud

- Introduction on IUCLID 6 and IUCLID 6 main functions
- **Exercise**

- Inquiry is created in IUCLID (Cloud or Application)
- An inquiry dossier must include the following:
  - Section 1.1 - Substance identification
  - Section 1.2 - Composition information
  - Section 1.4 - Analytical information
  - Section 14 - Inquiry information requirements

- The inquiry dossier is submitted to ECHA via REACH-IT
- Business rules check only (no completeness check), verification of the substance identity
- Use the Validation Assistant on your substance to find the business rule failures before submitting the dossier to REACH-IT

- As a result of the inquiry, ECHA gives you
  - An inquiry number that needs to be inserted to the Registration dossier (section 1.3)
  - Access to the co-registrants page in REACH-IT; it shows the existing and potential registrants of the same substance
  - The requested robust study summaries if a registration exists and the data is older than 12 years
  - The name of the company that submitted the data if a registration exists but is less than 12 years old

1. Import your substance dataset file to IUCLID
2. Find your substance
3. Change the view mode to REACH Inquiry to see only the relevant sections
4. Run the Validation Assistant (VA) on your substance dataset
5. One-by-one correct all the reported business rule failures in your substance dataset. Refresh the VA report to see that the error is gone.
6. Create the inquiry dossier and save it on your desktop

## First step

- Login to machine: **Password1!**
- Start Local IUCLID
- Open the Chrome browser
- Download the training materials from the IUCLID 6 website (link on your desktop:  
<http://iuclid6.echa.europa.eu/training-material>)

IUCLID > Training material



### Training material

#### IT Tools training - REACH Stakeholders' day

*ECHA, Helsinki, Finland, 4 April 2017*

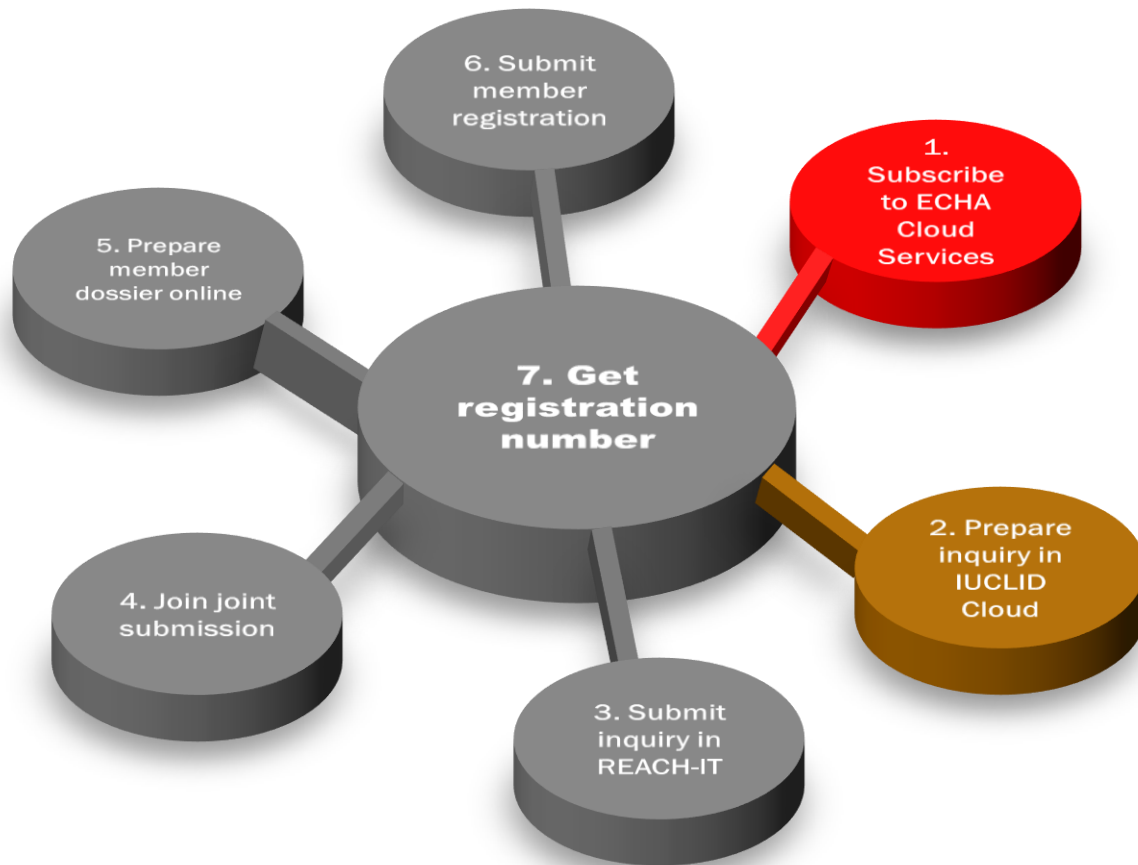
- Morning session (substance: paratraining sulfate)

Presentation | [IUCLID 6 substance dataset](#) | [Attachment for section 1.4](#) | [Exercise: online registration dossier with REACH-IT](#) | [Structural formula](#) | [Attachment for the REACH-IT online dossier creation](#)

- Afternoon session (substance: oxytraining sulfate)

Presentation | [IUCLID 6 substance dataset](#) | [Attachment for section 1.4](#) | [Exercise: online registration dossier with REACH-IT](#) | [Structural formula](#) | [Attachment for the REACH-IT online dossier creation](#)

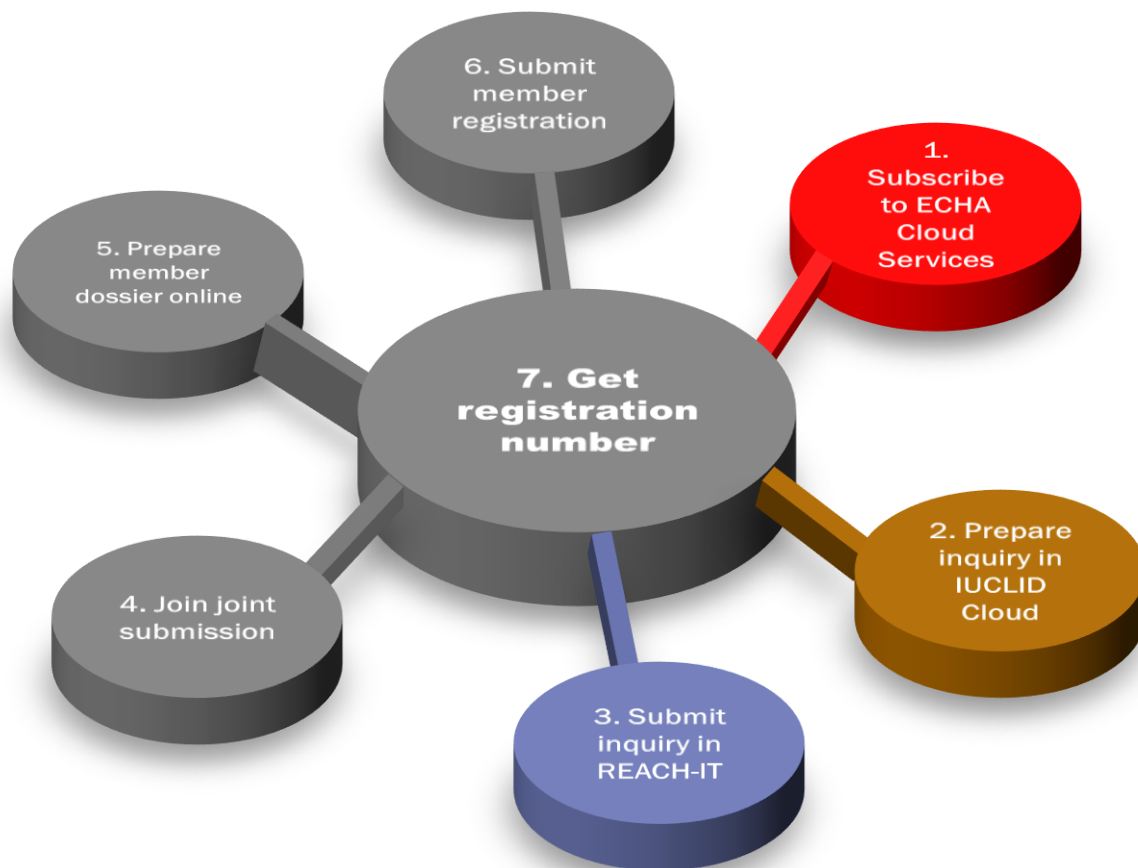




## 2

### Prepare inquiry in IUCLID Cloud

- Introduction on IUCLID 6 and IUCLID 6 main functions
- **Exercise**



3

## Submit inquiry in REACH-IT



Presentation

**REACH-IT**



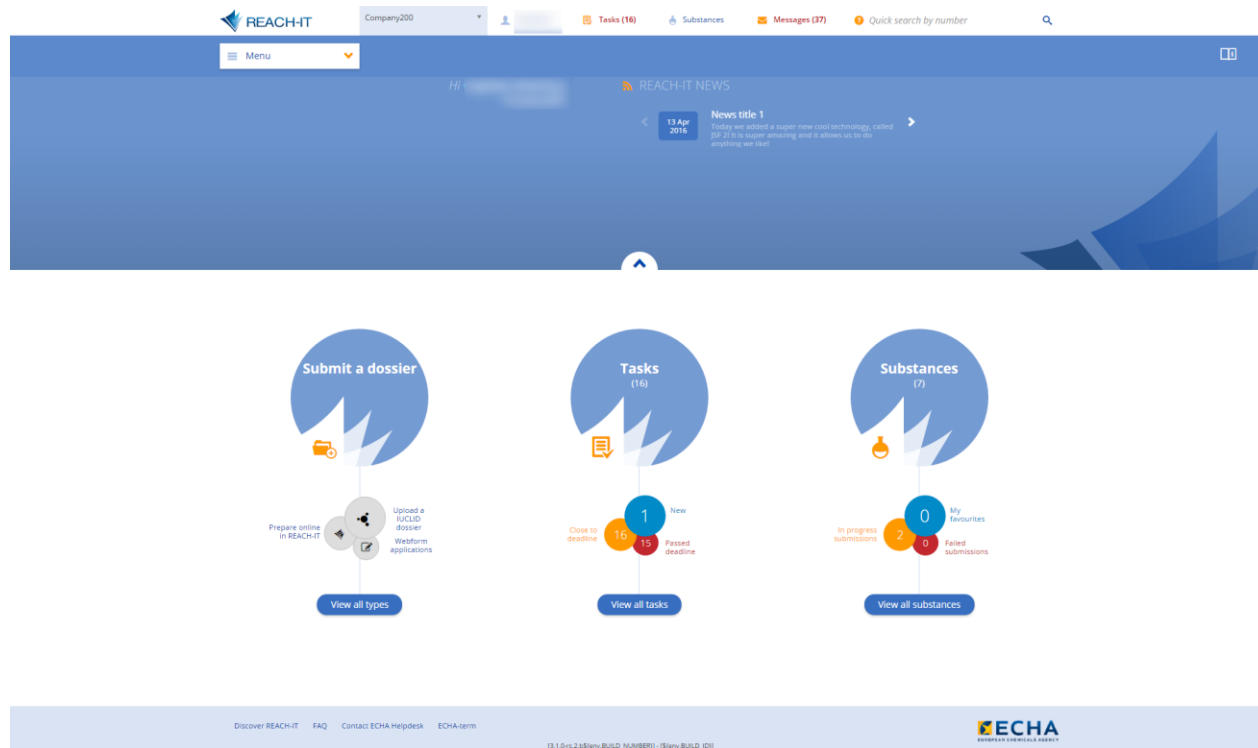
Intuitive user interface

Integrated help

Checklists available before submission

Easier identification of co-registrants and existing joint submissions

Online registration for members – no need to install IUCLID





REACH-IT Training Company TrainingCompany Tasks (1) Substances Messages Quick search by number

Menu

Hi Margot Mägi Training Company

REACH-IT NEWS

25 Aug 2015 REACH-IT SAT-IT-1 This is the SAT-IT-1 REACH-IT environment.

**Submit a dossier**



Prepare online in REACH-IT

- Upload a IUCLID dossier
- Webform applications

View all types

**Tasks (1)**



1 New

1 Close to deadline

0 Passed deadline

View all tasks

**Substances (0)**



0 My favourites

0 In progress submissions

0 Failed submissions

View all substances

Menu 

 **Submit**

[Submit a dossier](#)

[Alternative chemical name request](#)

- [Webform application](#)

[Application for authorisation](#)

- [Upload a IUCLID dossier](#)

[Classification and labelling notification](#)

- [Upload a IUCLID dossier](#)
- [Prepare and submit online In REACH-IT](#)
- [Manage group of manufacturers or Importers](#)

[Downstream user report – Authorisation](#)

- [Webform application](#)

[Downstream user report – Registration](#)

- [Upload a IUCLID dossier](#)
- [Webform application](#)

[Inquiry](#)

- [Upload a IUCLID dossier](#)
- [Prepare and submit online In REACH-IT](#)

[PPORD notification](#)

- [Upload a IUCLID dossier](#)

[Pre-registration](#)

- [Data holder information](#)
- [Late pre-registration](#)

[Registration](#)

- [Upload a IUCLID dossier](#)
- [Prepare and submit online In REACH-IT](#)
- [Claim notified substance](#)

[Substance in articles](#)

- [Upload a IUCLID dossier](#)
- [Webform application](#)

 **Search**

[Advanced search](#)

[Reference numbers](#)

[Submissions](#)

[Substances](#)

[Co-registrants](#)

[Pre-registrations and pre-SIEFs](#)

[Classification and labelling](#)

[Key documents](#)

[Invoices](#)

 **Joint submission**

[Create new](#)

[Join existing](#)

[Search and view](#)

 **Manage company**

[Company information](#)

[Company size](#)

[Contacts](#)

[Email notification settings](#)

[Legal entity change](#)

- [Initiate a legal entity change](#)
- [Search or finalise a legal entity change](#)
- [Create and export an assets list](#)

[Third party representatives](#)

 [Tasks](#)

 [Messages](#)

 [Terms and Conditions](#)

 [Logout](#)

The submission process cannot be saved so ensure you have all the required information before you begin.

Dossier type: \* Registration

Submission type: \*

Select the option which defines the company's ownership structure. The options "Linked company" and "Partner company" can be combined. Please note that the off-structure options are not available. You can find more information on the ECHA website (<http://echa.europa.eu/support/small-and-medium-sized-enterprises-smes/how-to-determine-the-company-size-category>). An error message will be displayed if you select an invalid option.

Topic help

Checklists in wizards

Are you ready to submit your dossier? Before continuing, make sure that:

- ✔ You are part of the **joint submission**, if one exists for your substance.
- ✔ The **company size is correct**. You can find out how to determine the company size if you are unsure.
- ✔ The **VAT number and billing address** in REACH-IT are up to date, and optionally you have a purchase order number: they will appear on the invoice.
- ✔ The **contact persons** for this dossier has been defined, and the **contact details** are up to date.

certain information from the dossier will be published on the website without further notice. Use the notification plugin in IUCLID to ensure that this information will be published.

Continue to upload dossier >

Page help

**Need help?**

You have now launched the submission wizard for your selected submission type. The submission wizard will guide you through the steps of the submission process.

In each step of the submission process you will find customised information relevant for your submission type. Remember to refer to the checklist on each wizard step to receive detailed assistance for your submission.

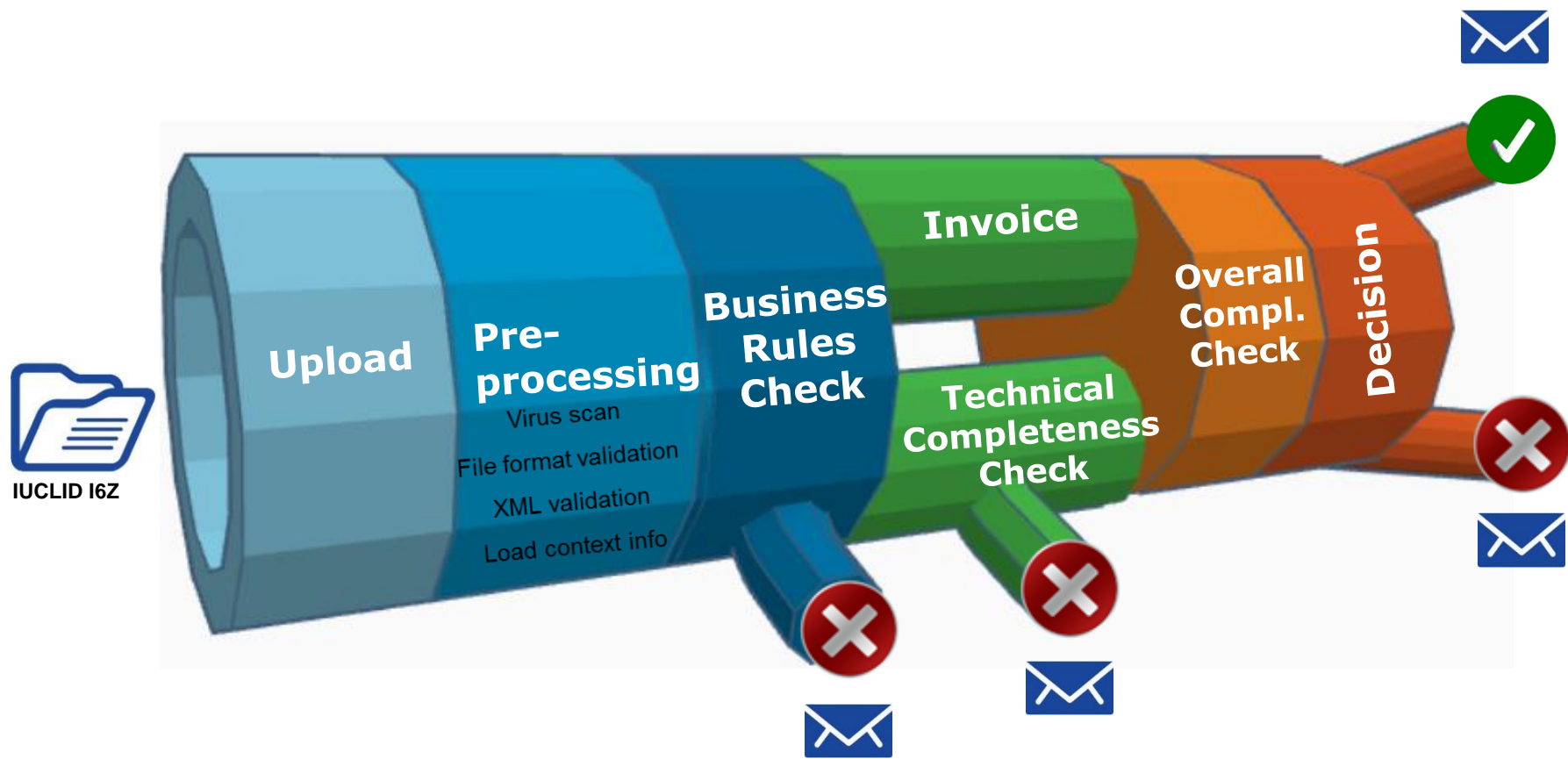
In the *Submission details* step, you will first choose the dossier type applicable to your submission: application for authorisation, classification and labelling notification, downstream user report, inquiry, PPOD notification, registration or substance in articles. If you are submitting a Registration, you will also need to specify the submission type: individual or joint submission. Remember that you will not be able to submit an individual registration if a registration for the same substance already exists. If this is the case, you need to contact your co-registrants and join the joint submission. You may search for your co-registrants and existing joint submissions on the *Advanced search* page in REACH-IT.

In the *Upload dossier* step, you can upload your IUCLID dossier. If the upload is successful, you will see an application for authorisation details. You will also see if your IUCLID dossier are available. Details on your REACH-IT application are available. If you are not successful or you want to upload a new dossier with another one, you need to click on *Want to upload a new file?* More information on how to prepare your dossier can be found on the [IUCLID manuals page](#).

In the *Additional details* step, you may specify and edit additional information depending on your submission type. If you are submitting an application for...

Turn on all In-page help items

# Regulatory processing by the Agency

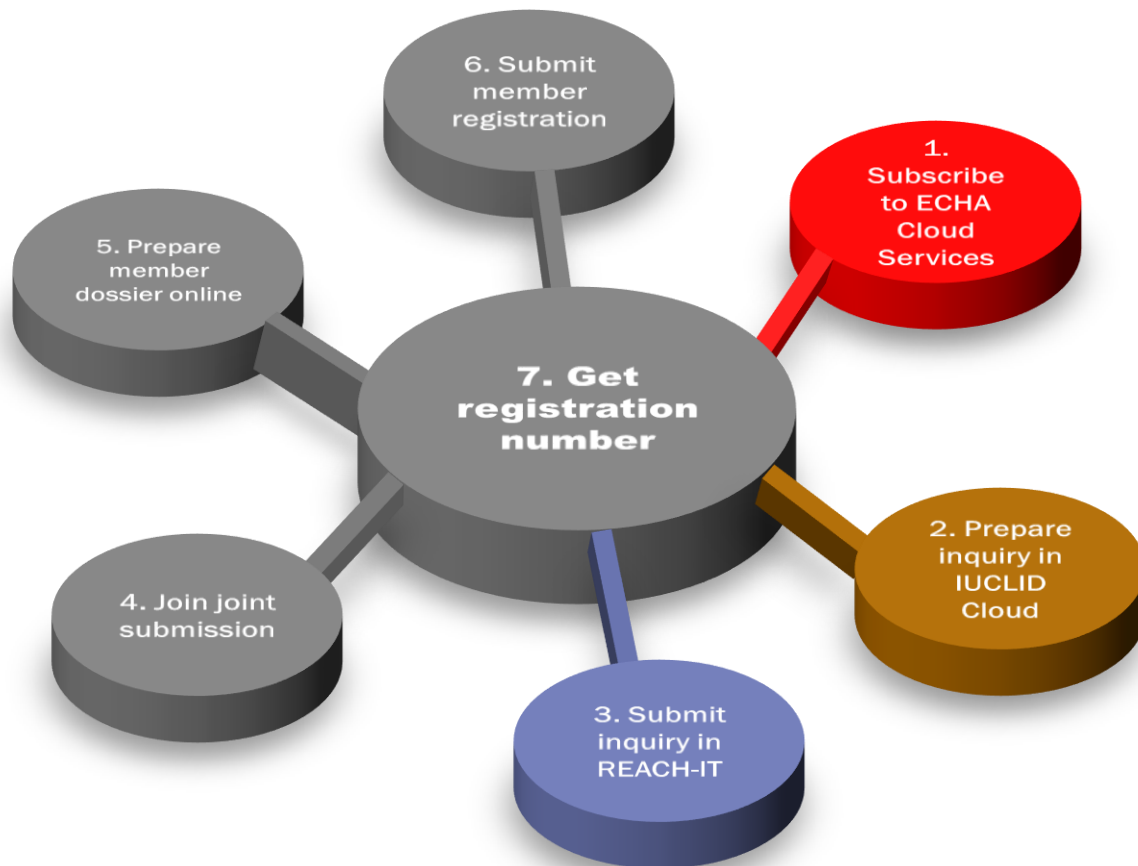




## Submit a dossier



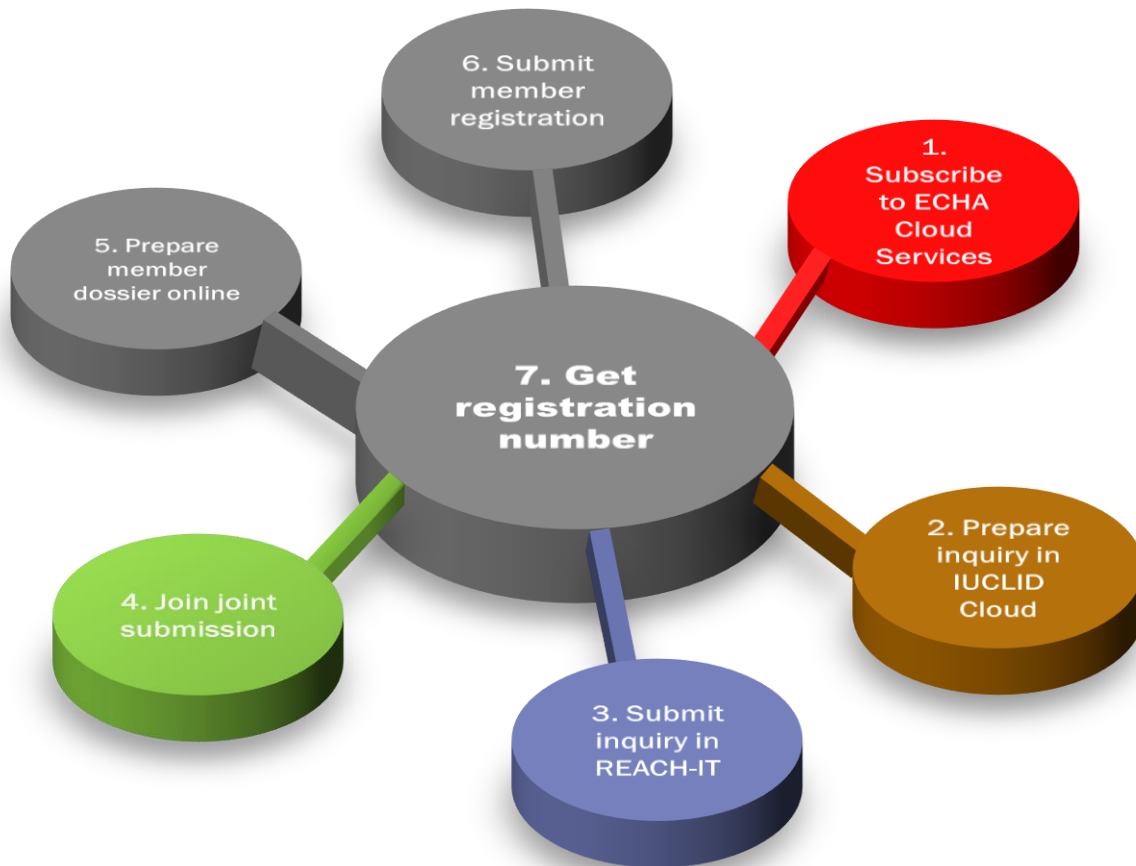
- Upload a IUCLID dossier
- Webform applications
- Prepare online in REACH-IT



3

## Submit inquiry in REACH-IT

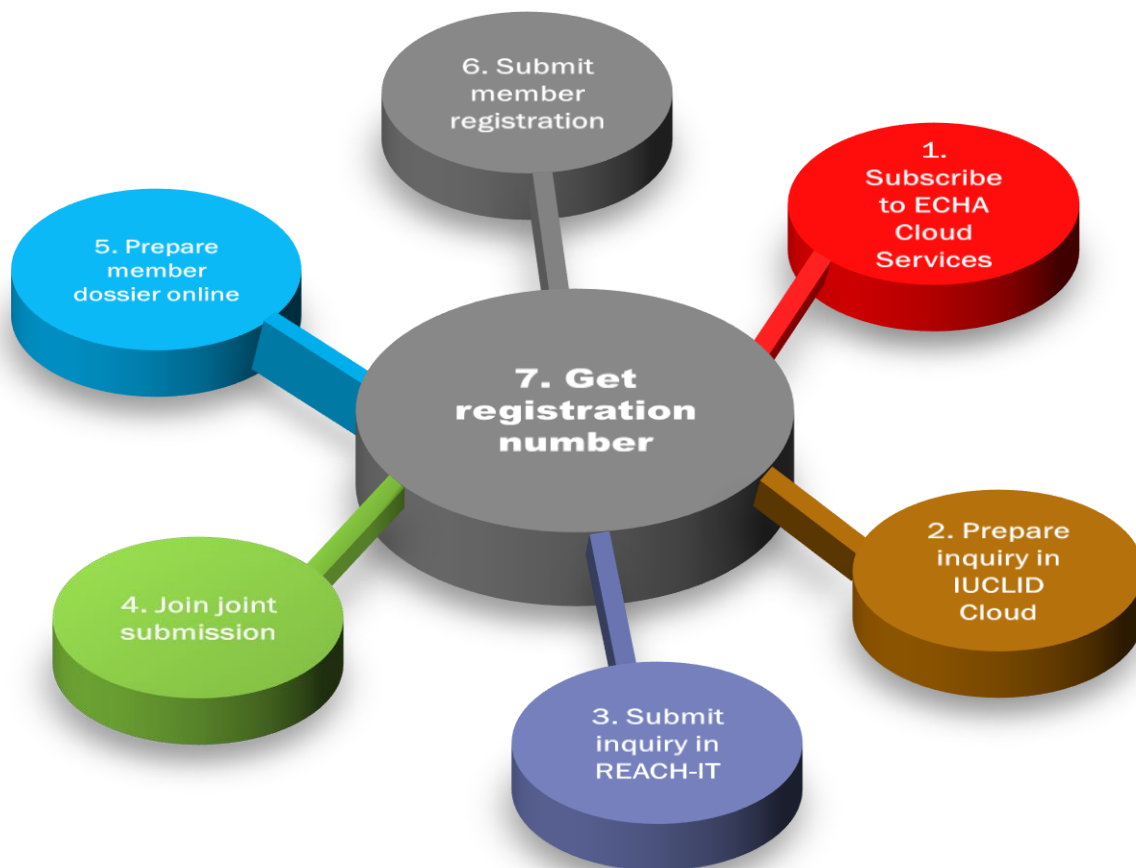
- Submit your inquiry dossier in REACH-IT
- Wait for the reference number
- Visit the co-registrants page



# 4

## Join joint submission

- Find the joint submission
- Use the joint submission name and token combination to join the joint submission



5

## Prepare member dossier online



Presentation

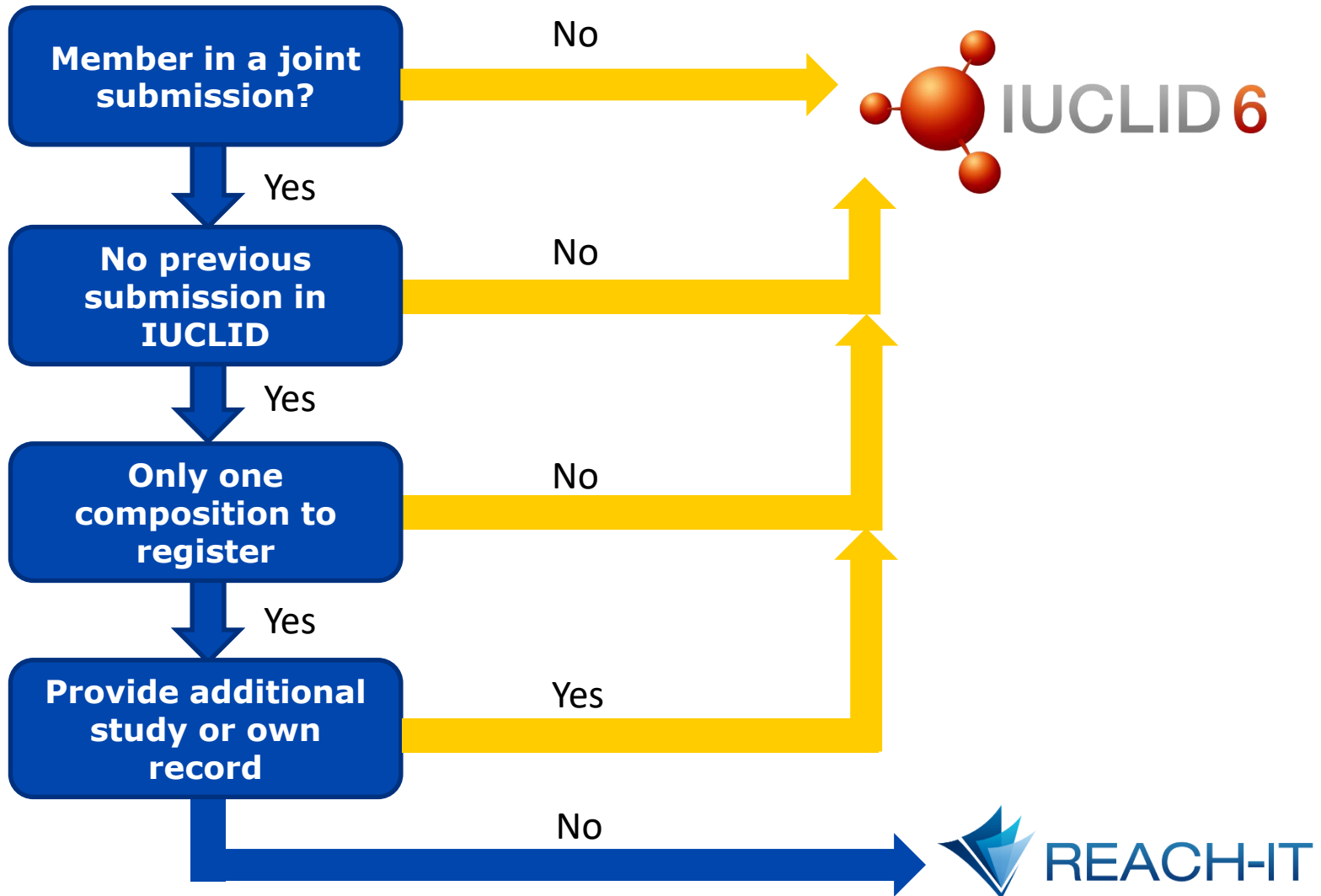
# Online registration as a member



## Create and submit a member dossier online

- Simplified way to create a member registration dossier directly in REACH-IT
- Step-by-step wizard with online help features
- Compulsory information highlighted
- Pre-filled information and reduced number of fields
- Automatic saving and possibility to update

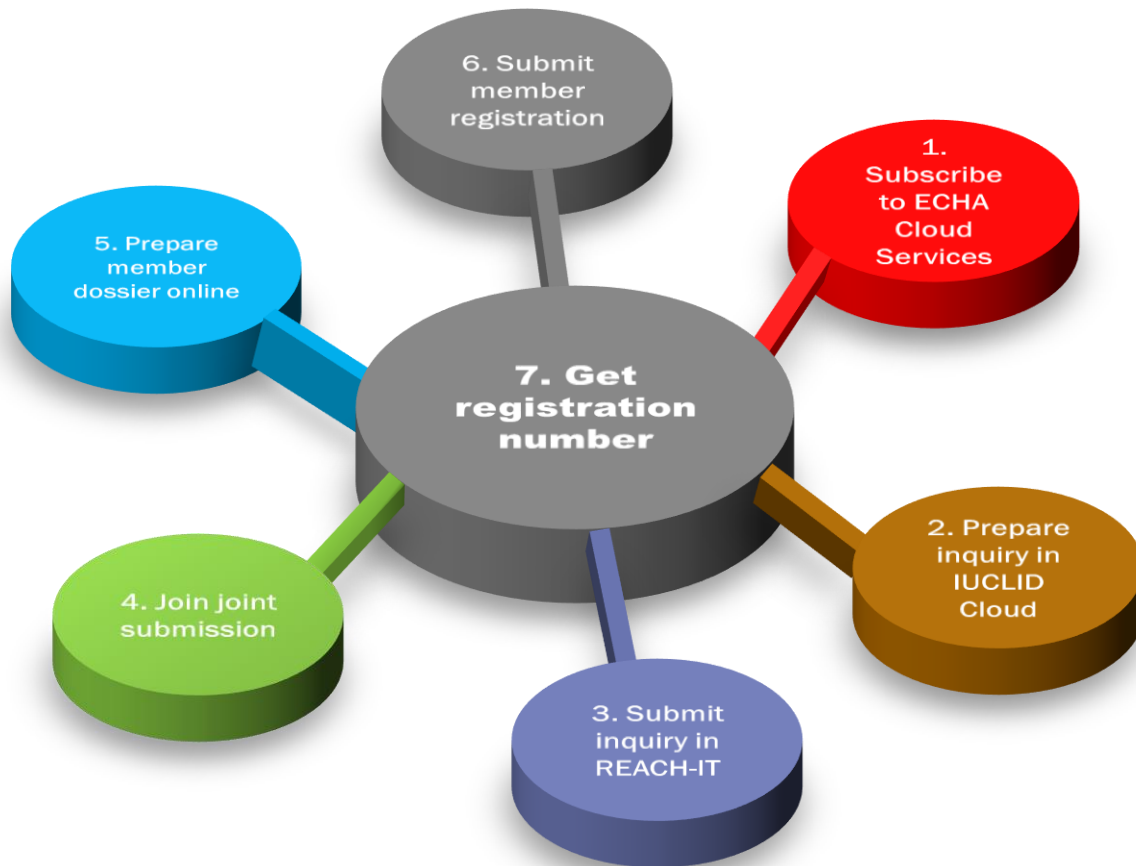
## Conditions



## Required data for members

- Same data in IUCLID and in REACH-IT
- Every co-registrant of the joint submission:
  - Substance identity, including impurities
  - Tonnages of the substance
  - Uses and conditions of use through the life-cycle
- Co-registrants 10 tonnes per year or more:
  - Attach chemical safety report, unless agreed with the lead that he will submit on behalf of the members
- Members who need to submit own classification and labelling can provide it too
- Confidentiality claims can be indicated





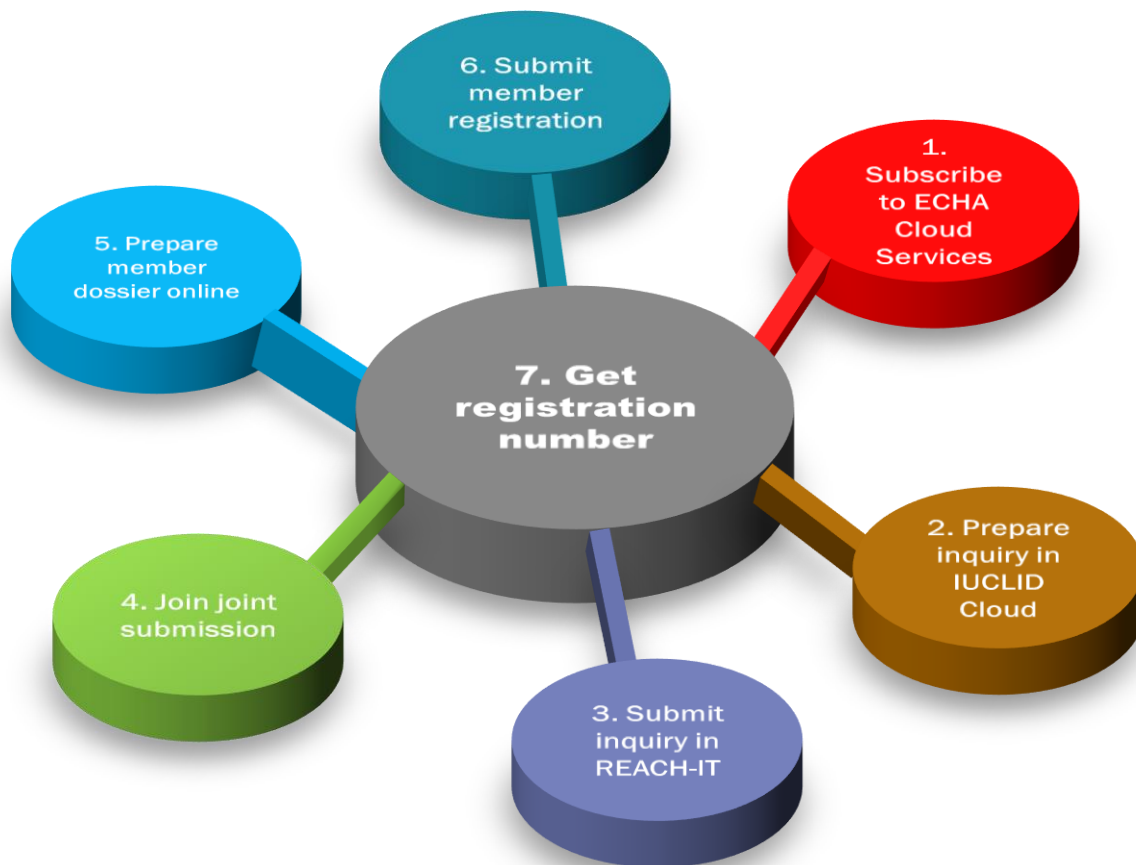
5

## Prepare member dossier online

- Start from the joint submission page
- Fill the necessary information to continue to the next step

# 6

## Submit member registration



- Review the information provided
- Add your contact details



7

## Get registration number

- Find the invoice in your tasks and watch out for the deadline

1

- Find the joint submission – Use the “Search for other joint submissions” functionality if you have pre-registered or inquired

2

- Join the joint submission

3

- Create the dossier online: start from the joint submission page

4

- Read the tasks and messages (BRs, TCC, Invoice): pay the invoice

5

- Receive the registration number



## Bonus

### Subscribe to ECHA Cloud Services

- Open the Cloud URL
- Login and subscribe
- Upload IUCLID dossier

# Today achievements



## Today achievements

- Used the IUCLID Cloud for the first time
- Created a dossier in IUCLID
- Found and joined the joint submission
- Created a member dossier online in REACH-IT
- Received a registration number for your member dossier

# Thank you!

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