Overview of Dossier Creation and Submission

How to Prepare and Submit
Member Dossier Webinar
5th March 2013

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ECHA

Agenda

Overview of the dossier creation & submission

- Information requirements
- Dossier creation (wizard)
- Verifying the dossier before submission (plug-ins)
- Confirming membership in REACH-IT
- Submitting the member dossier
- Latest IUCLID version

Preparing and submitting dossiers

- Webinars:

  - General principles of dossier preparation and submission

    http://echa.europa.eu/web/guest/view-article/-/journal_content/2dff7a95-55f4-440d-82b6-a7b615d2b7af

- Manuals:

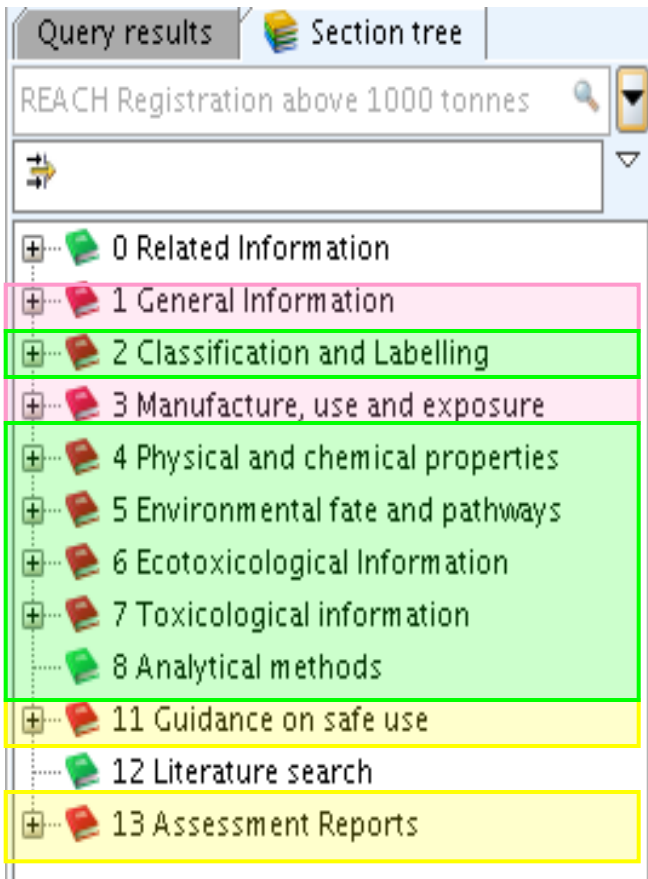 - Industry User Manual 6. Dossier Submission

    http://echa.europa.eu/documents/10162/13654/ium6_dossier_submission_en.pdf

Information Requirements

Information Requirements

Lead   Member

Private data submitted by the
LEAD and the MEMBER

Data submitted only by the
LEAD (if not opted-out)

Data submitted either by the
LEAD or individually

What is needed in a Member Registration Dossier
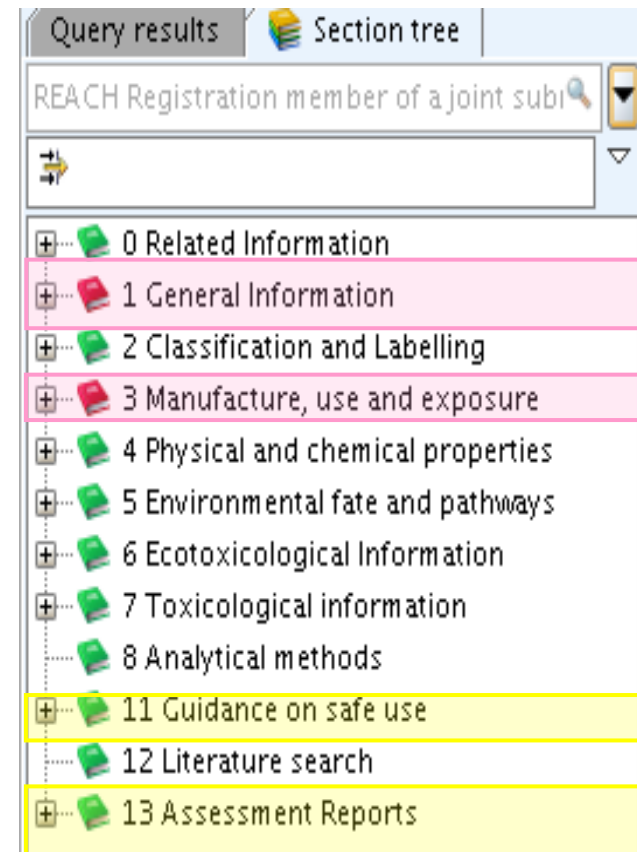
Section 1 – General Information

- 1.1 – Identification
- 1.2 – Composition
- 1.3 - Identifiers
- 1.4 – Analytical information
- 1.7 – Suppliers (solely for only reps)
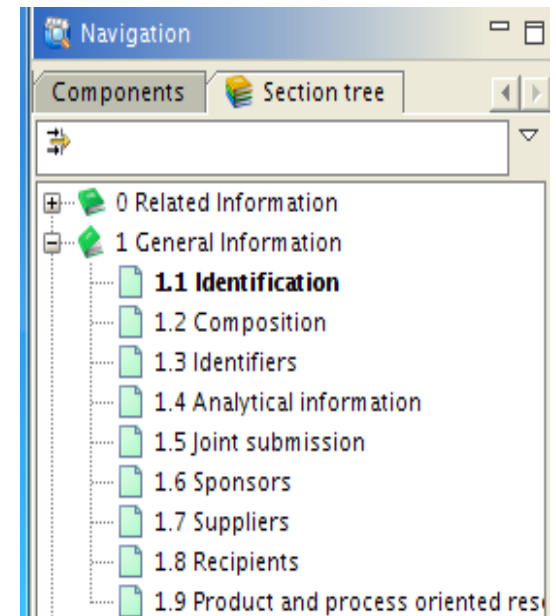
What is needed in a Member Registration Dossier
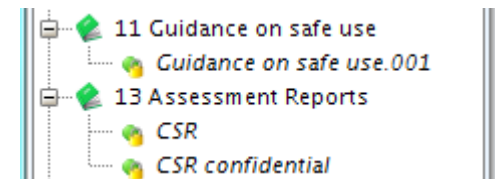
Section 3 – Manufacture, Use, and Exposure

- 3.1 – Technological Process
- 3.2 – Estimated quantity to register
- 3.3 – Sites
- 3.4 – Information on Mixtures
- 3.5 – Life Cycle Description
- 3.6 – Uses Advised against
- 3.7 – Exposure Scenarios
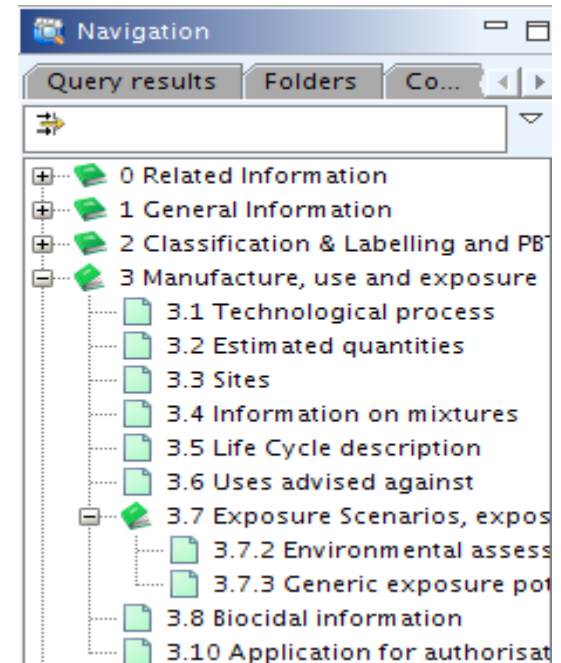
What is needed in a Member Registration Dossier

Section 11 – Guidance on Safe Use

- Yes – If Lead not providing
- No – If provided by Lead

Section 13 – Chemical Safety Report

- Yes – If Lead not providing
- No – If provided by Lead

Dossier Creation Wizard

Dossier creation

Raw data-base
Enter/edit data

Dossier creation wizard

Step 1.

Select: member of a joint submission template
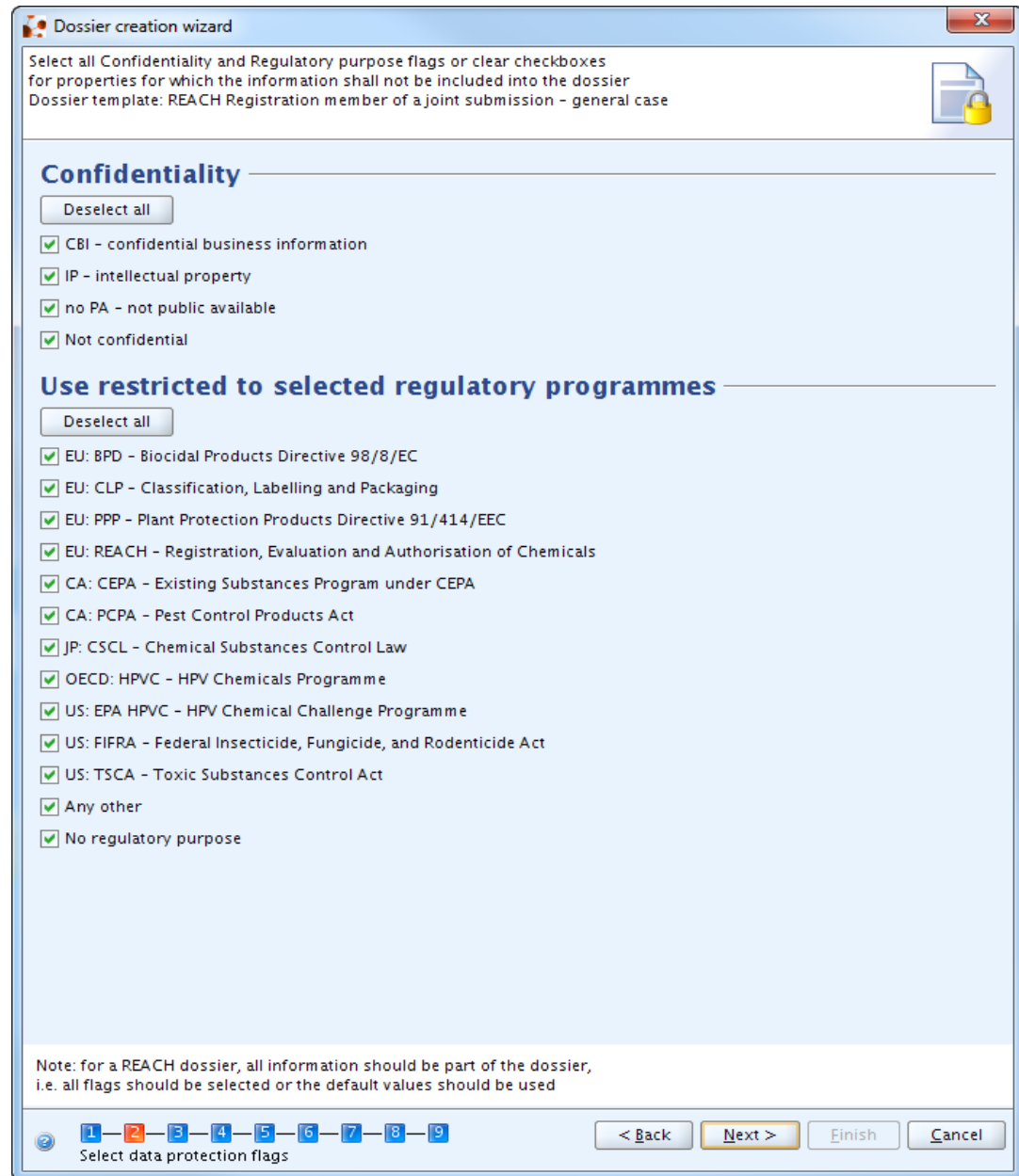
- general case
- intermediates
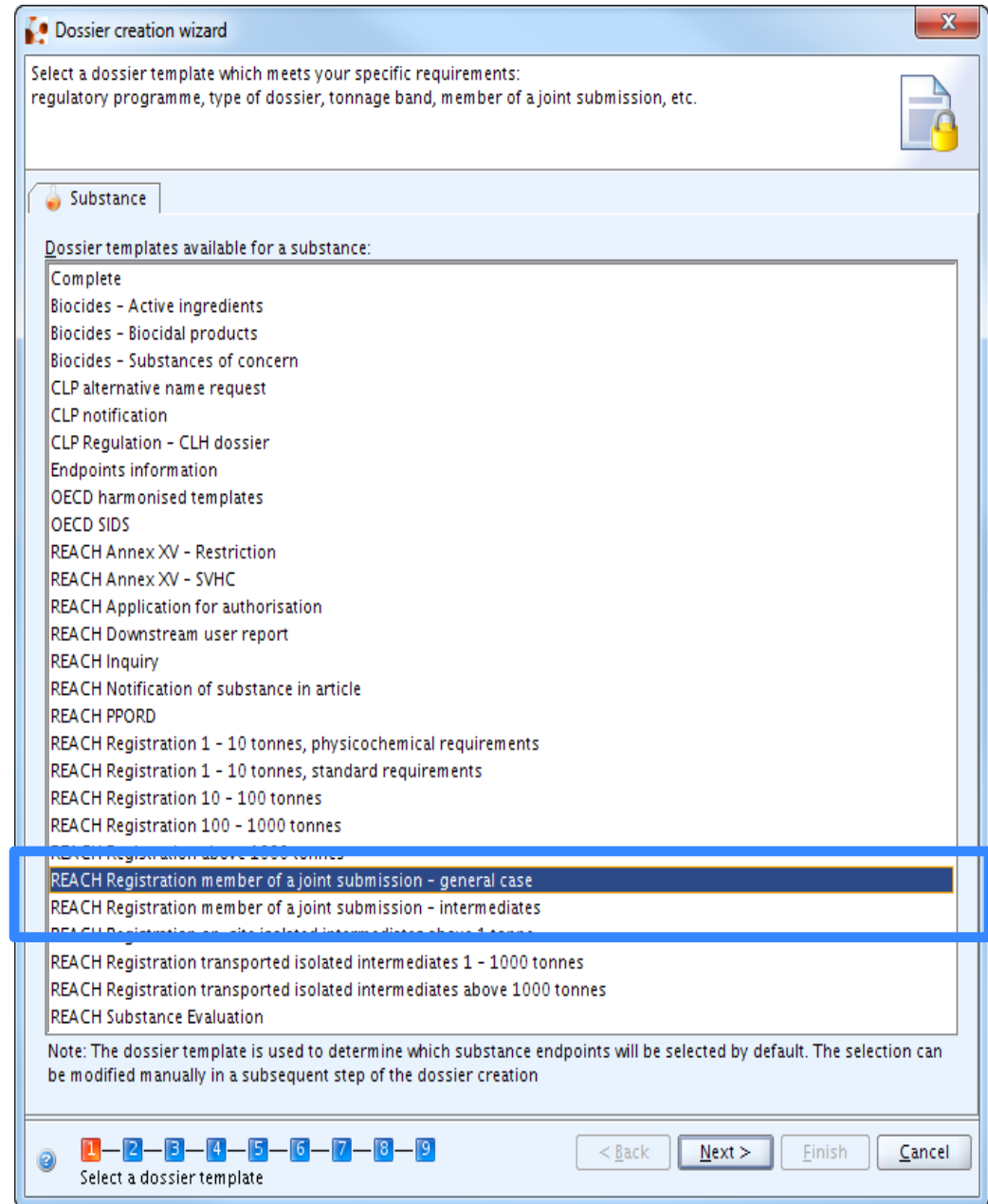
Dossier creation wizard

Step 2.

We suggest that you select all the flags

Dossier creation wizard

Select all Confidentiality and Regulatory purpose flags or clear checkboxes
for properties for which the information shall not be included into the dossier
Dossier template: REACH Registration member of a joint submission – general case

Confidentiality

[Deselect all]

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

Use restricted to selected regulatory programmes

[Deselect all]

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

Note: for a REACH dossier, all information should be part of the dossier,
i.e. all flags should be selected or the default values should be used
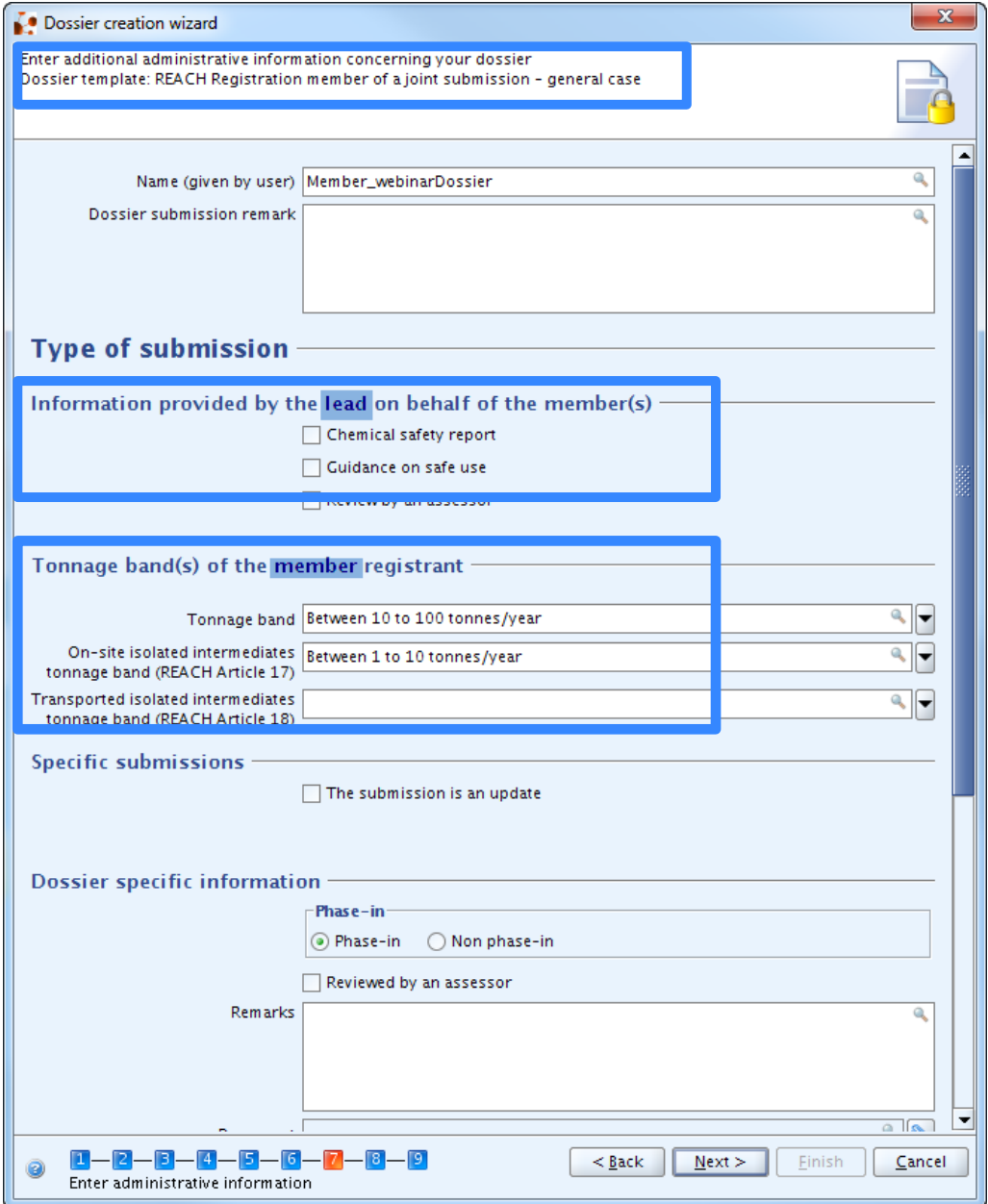
1—2—3—4—5—6—7—8—9   [< Back] [Next >] [Finish] [Cancel]
Select data protection flags

Dossier creation wizard

Step 7.

Select the Dossier Header information
and define your tonnage band

Verifying dossier before submission

Verifying the Dossier Before Submission

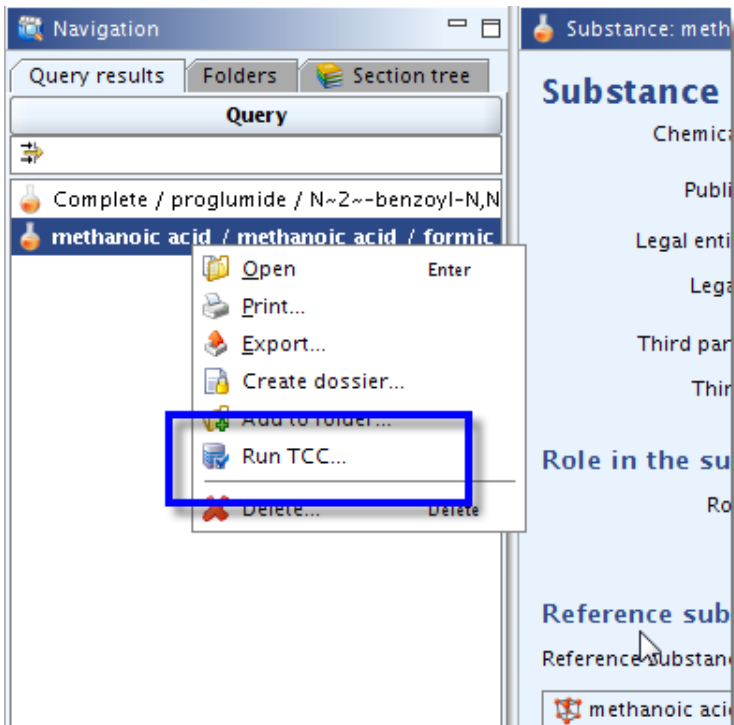Plug-ins to use:

TCC plug-in   Dissemination plug-in   Fee Calculator
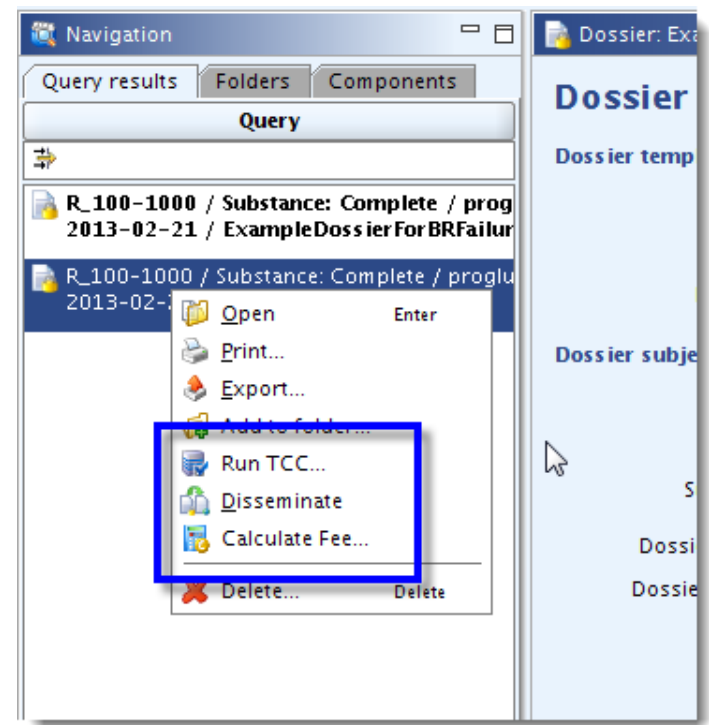
- Available for free from the IUCLID5 website
- Use the latest version

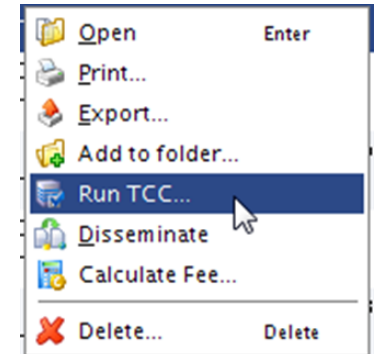# How to run the plug-ins:

substance dataset   final dossier

- Right click on the substance/dossier and select the plug-in

The TCC plug-in

- Checks most of the Business Rules

- Simulates the Technical Completeness Check

- Verifies if minimum requirements are fulfilled

  - Checks relevant sections and endpoints based on tonnage band

- Two different results

  - Warning

  - Failure

- Can be run on the substance dataset or on dossier

Run the TCC plug-in:
Check that you have the latest version

Current plugin is up to date.

1 — 2 — 3
Define check options

< Back   Next >   Finish   Cancel

TCC engine version: 7.00   Business rules version: 2.2.10   Completeness rules version: 2.2.8

1 — 2 — 3
Results

< Back   Next >   Finish   Cancel

Run the TCC plug-in: Filter rules

Run the TCC plug-in:
When no failures are found

When no TCC or BR failures are found in the dossier or on the substance dataset, this is reported by the following disclaimer messages:

echa.europa.eu

Run the TCC plug-in:
New feature: Dossier Quality Assistant

The TCC plug-in
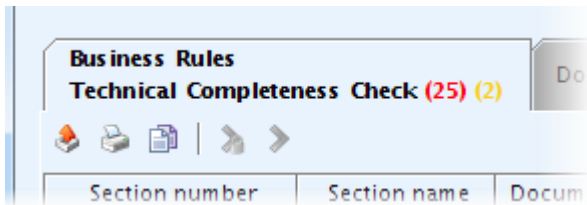
- BR and TCC failure → Dossier fails BR and TCC in REACH-IT

- BR and TCC warning is not an indication of that your dossier will fail the Business Rules and Technical Completeness Check, but it suggests that some information that should normally be in your registration dossier is missing.

- BR and TCC disclaimer no BR and TCC failures found
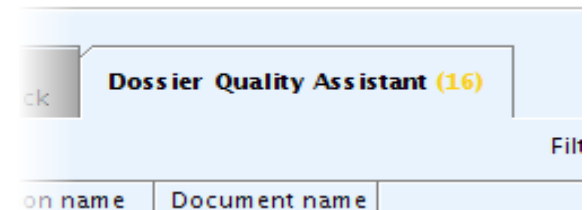
- Dossier Quality warnings are recommendations on how to improve the consistency of the selected information

- Substance Identity warnings are recommendations on how to improve the consistency of the reported substance identity information

Run the Fee Calculation plug-in

Run the Dissemination plug-in

Dossier export

Dossier database
Snapshot
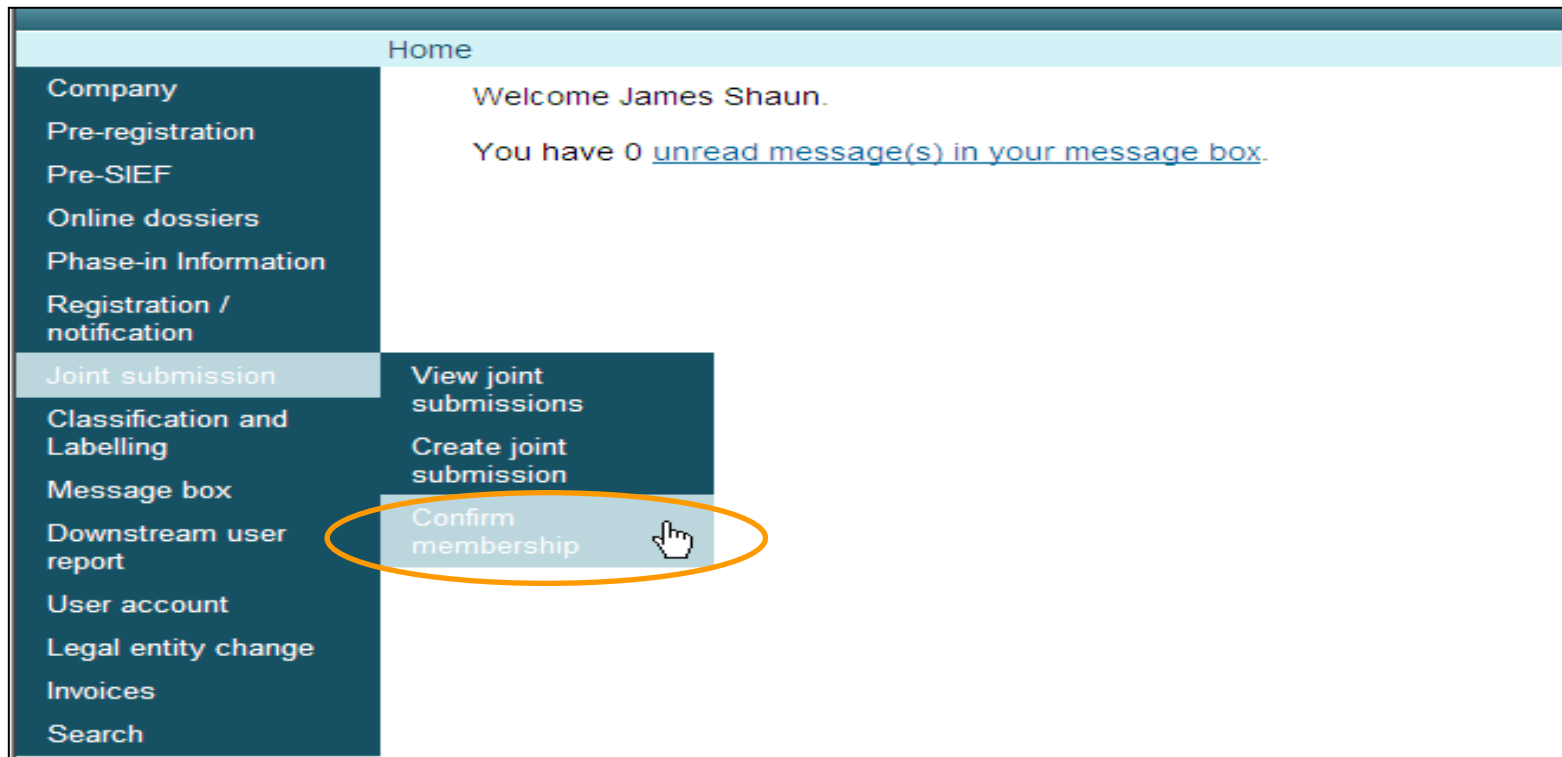
Confirming membership in REACH-IT

Confirming membership of the Joint Submission

- As a member registrant you need to confirm your membership in the Joint Submission in REACH-IT

- In order to join a Joint Submission you need the <u>exact name</u> of the joint submission <u>and</u> the <u>security token</u> (access code). This information needs to be provided to you by the Lead registrant of the Joint Submission

Confirming membership of the Joint Submission

Step 1: Select confirm membership

Confirming membership of the Joint Submission

Step 2: Provide exact name and token of the JS

The most common error made is entering an incorrect joint submission name or token string. In order to avoid that, copy-paste the information provided by the lead registrant

Tokens have an expiry date of 30 days after they are issued. If you did not join during this time then ask the Lead for a new token

Confirming membership of the Joint Submission

Step 3: Select a contact name

Confirming membership of the Joint Submission

Step 4: Select third party representative (if any)

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Confirming membership of the Joint Submission

Step 5: Review entered information and confirm membership

Confirming membership of the Joint Submission

You have successfully confirmed your membership!

Confirming membership of the Joint Submission

Joint Submission details

Submitting dossier in REACH-IT
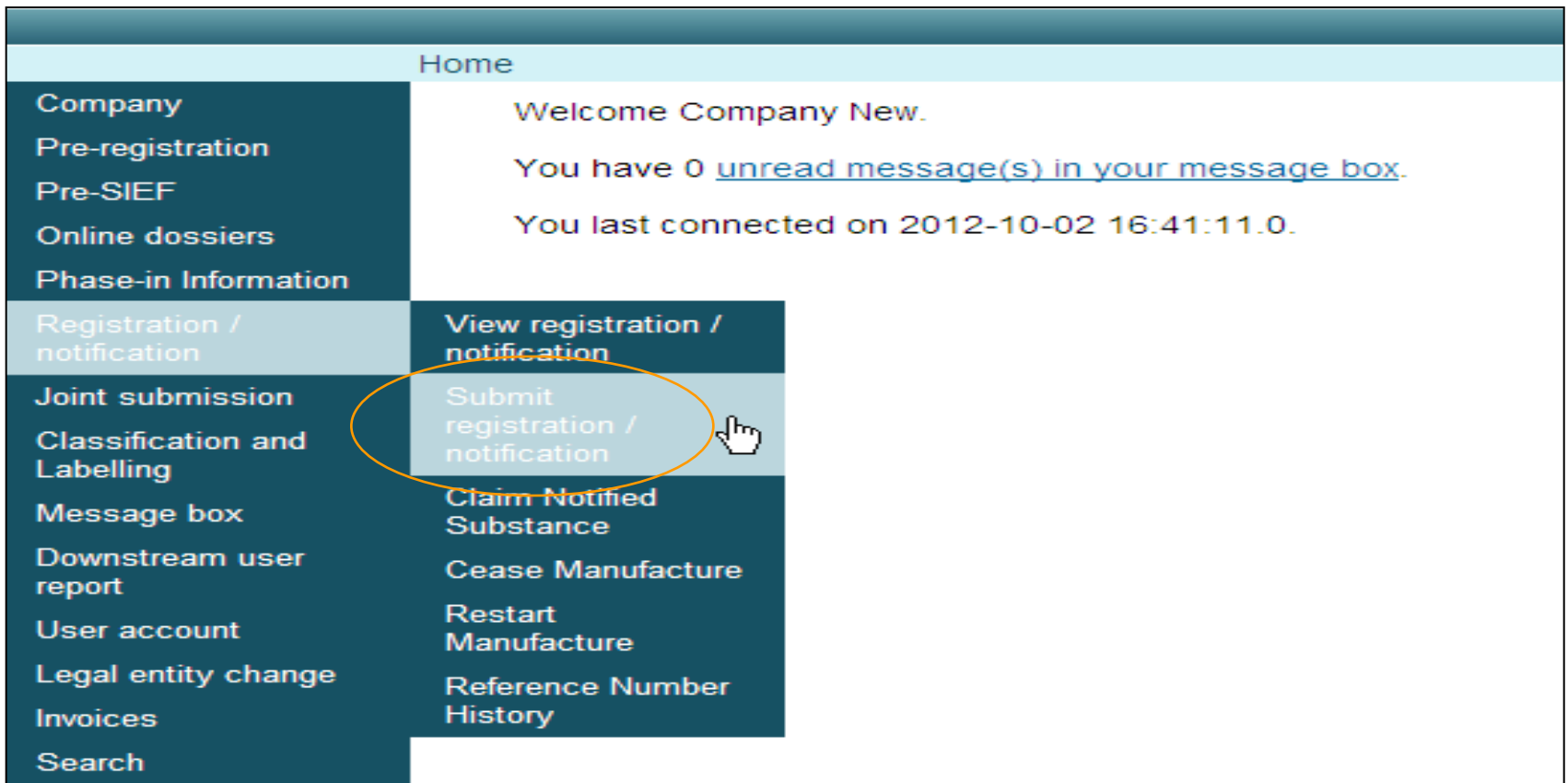
Submitting the dossier

A member may submit the member dossier:

- Only once the joint submission has been created,
- membership has been confirmed and
- the Lead has submitted the Lead dossier

Submitting the dossier
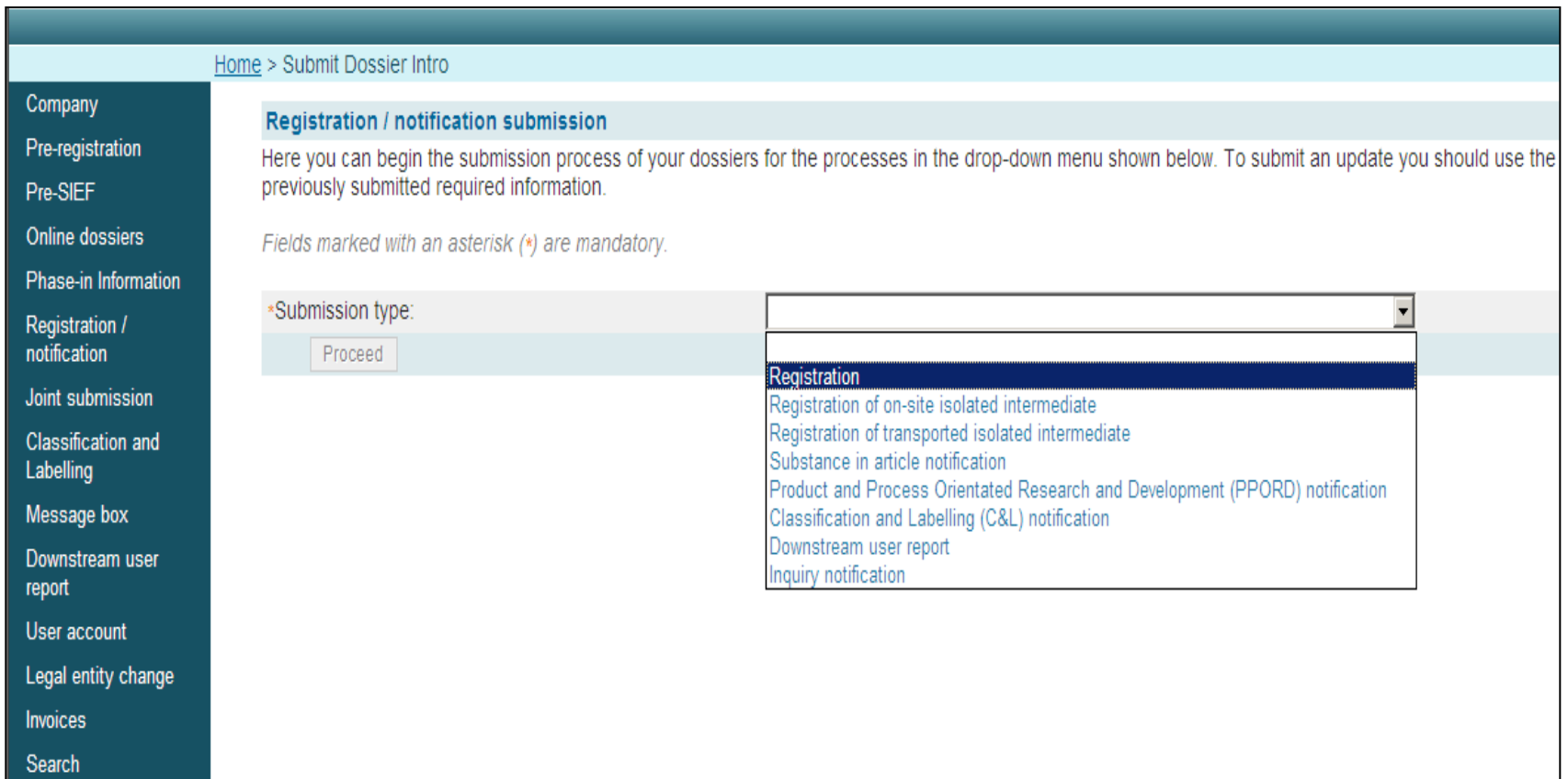
Step 1: Select Submit registration/notification

Submitting the dossier

Step 2: Select the correct type of registration

Submitting the dossier

Step 3: Carefully read declaration and enter joint
submission name

Submitting the dossier

Step 4: Upload file and submit dossier

Submitting the dossier

Step 5: Confirm submission

Submitting the dossier

You have successfully uploaded your dossier !

Home > Submit Dossier Intro > Dossier Submission Successful

Company
Pre-registration
Pre-SIEF
Online dossiers
Phase-in Information
Registration / notification
Joint submission
Classification and Labelling
Message box
Downstream user report
User account
Legal entity change
Invoices
Search

Your dossier has been successfully uploaded. Please find below the preliminary submission number.

Registration

Preliminary submission number

Your dossier has received the following preliminary submission number: **PR143227-19** .

A report indicating the status of this dossier will be available in your Message box shortly.
Please use this preliminary submission number if you need to contact the Agency about this dossier, until you receive a

Your dossier is under examination by our IT systems to ensure that as a valid dossier it can be correctly processed. Fo submission date and submission number.

You will receive the reference number upon successful processing of this dossier by ECHA's systems.

At any time you can also consult the status of your dossier and the report in the menu "Registration/notification \ View r

Submitting the dossier

Check messages in your REACH-IT account

Is my IUCLID version up to date?

Which version of IUCLID do you have?

To see the version of IUCLID from the interface, go to Help / About.

If the version is 5.4.1, it can be used to create a dossier. If not, read on.

ECHA strongly recommends that you do the following, as soon as possible:

1) Back-up your IUCLID data

2) Install Java 7

3) Upgrade IUCLID to 5.4.1

ECHA recommends this because versions of IUCLID prior to 5.4.1 work only with Java 6, and soon updates to Java 6 will no longer be made. This is a security issue.
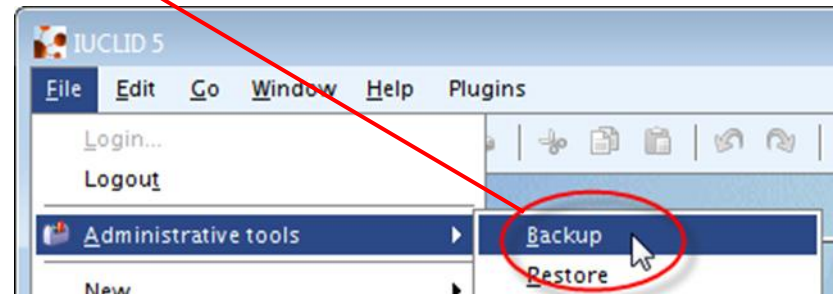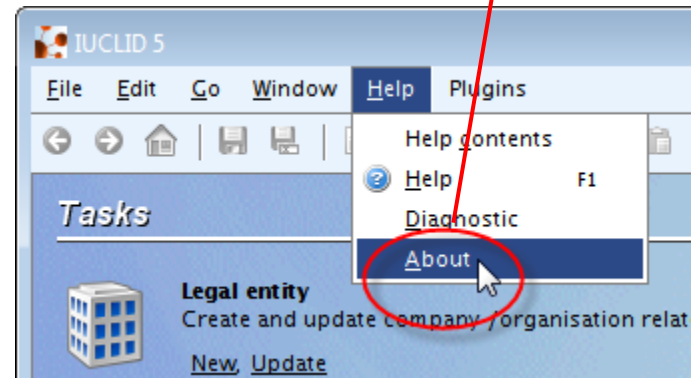
How do I upgrade to IUCLID 5.4.1?

In all cases, the installer for Microsoft Windows can be used.

For IUCLID 5.4.0 or 5.3.x, use the upgrade option of the installer.

◉ Upgrade from IUCLID 5.4.0 to 5.4.1   or   ◉ Upgrade from IUCLID 5.3.x to 5.4.1

For IUCLID 5.2.x or earlier, use the installer to make a new installation of 5.4.1, and then use the restore function to transfer the data from your backup into the installation of 5.4.1.

◉ Make a fresh installation of IUCLID 5.4.1

When performing the fresh installation, on page 3 of the installer, change the database name from the default value to **iuclid541**, as shown below.

Database name:* iuclid541

Database user name:* iuclid5

Be careful to launch IUCLID 5.4.1 using the newly created icon.

IUCLID 5.4.1

Key Messages

- Run the TCC plug-in both on the substance dataset AND on the dossier

- Make sure you have the latest software (IUCLID, plug-ins, Java)

- Confirm membership of joint submission

- Members can only submit their dossiers after Lead has passed business rules

- Contact ECHA Helpdesk

Thank you!