

ECHA's REACH-IT and IUCLID workshop

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IUCLID training – Part II

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The workshop is undertaken with funding by the European Union - supported by the Instrument for Pre-accession Assistance (IPA) project entitled "Preparatory measures for the participation of candidate countries and potential candidates in and their cooperation with the European Chemicals Agency (ECHA)".

Agenda:

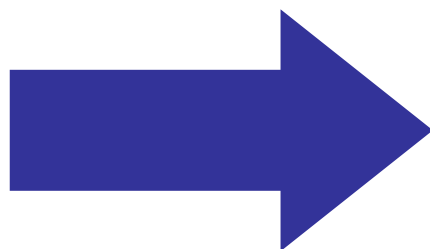
- Dossier creation
- Hands on exercise
- IUCLID plug-ins
- Hands on exercise

IUCLID Dossier

- Starting point – Substance dataset

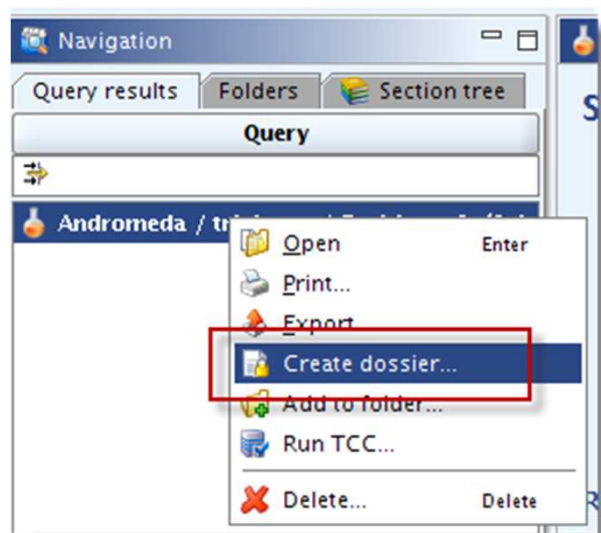
Dataset

Dossier



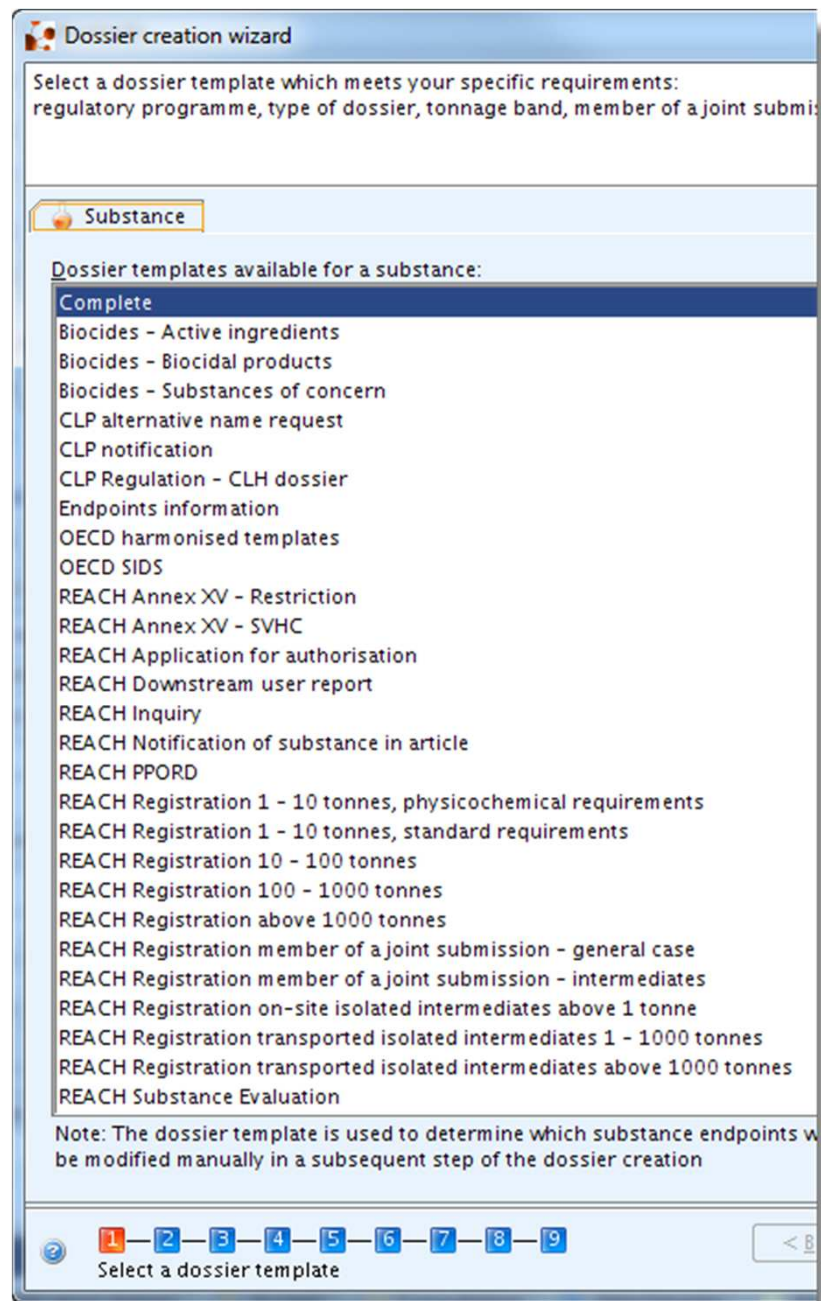
IUCLID Dossier creation

- Select the correct dataset



Follow the steps of the dossier creation wizard

IUCLID Dossier creation - templates



IUCLID Dossier – Individual, Lead Member

- Individual submission tonnage band = indicated in the dossier **template name**
- Joint submission tonnage band = indicated in the dossier **template name** (of the lead dossier)
- Joint submission Lead tonnage band = indicated in the **dossier header**
- **Member** tonnage band = indicated in the **dossier header**

IUCLID Dossier creation step 2

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 above 1000 tonnes

Confidentiality

Select all

CBI - confidential business information

IP - intellectual property

no PA - not public available

Not confidential

Use restricted to selected regulatory programmes

Select all

EU: BPD - Biocidal Products Directive 98/8/EC

EU: CLP - Classification, Labelling and Packaging

EU: PPP - Plant Protection Products Directive 91/414/EEC

EU: REACH - Registration, Evaluation and Authorisation of Chemicals

CA: CEPA - Existing Substances Program under CEPA

CA: PCPA - Pest Control Products Act

JP: CSCL - Chemical Substances Control Law

OECD: HPVC - HPV Chemicals Programme

US: EPA HPVC - HPV Chemical Challenge Programme

US: FIFRA - Federal Insecticide, Fungicide, and Rodenticide Act

US: TSCA - Toxic Substances Control Act

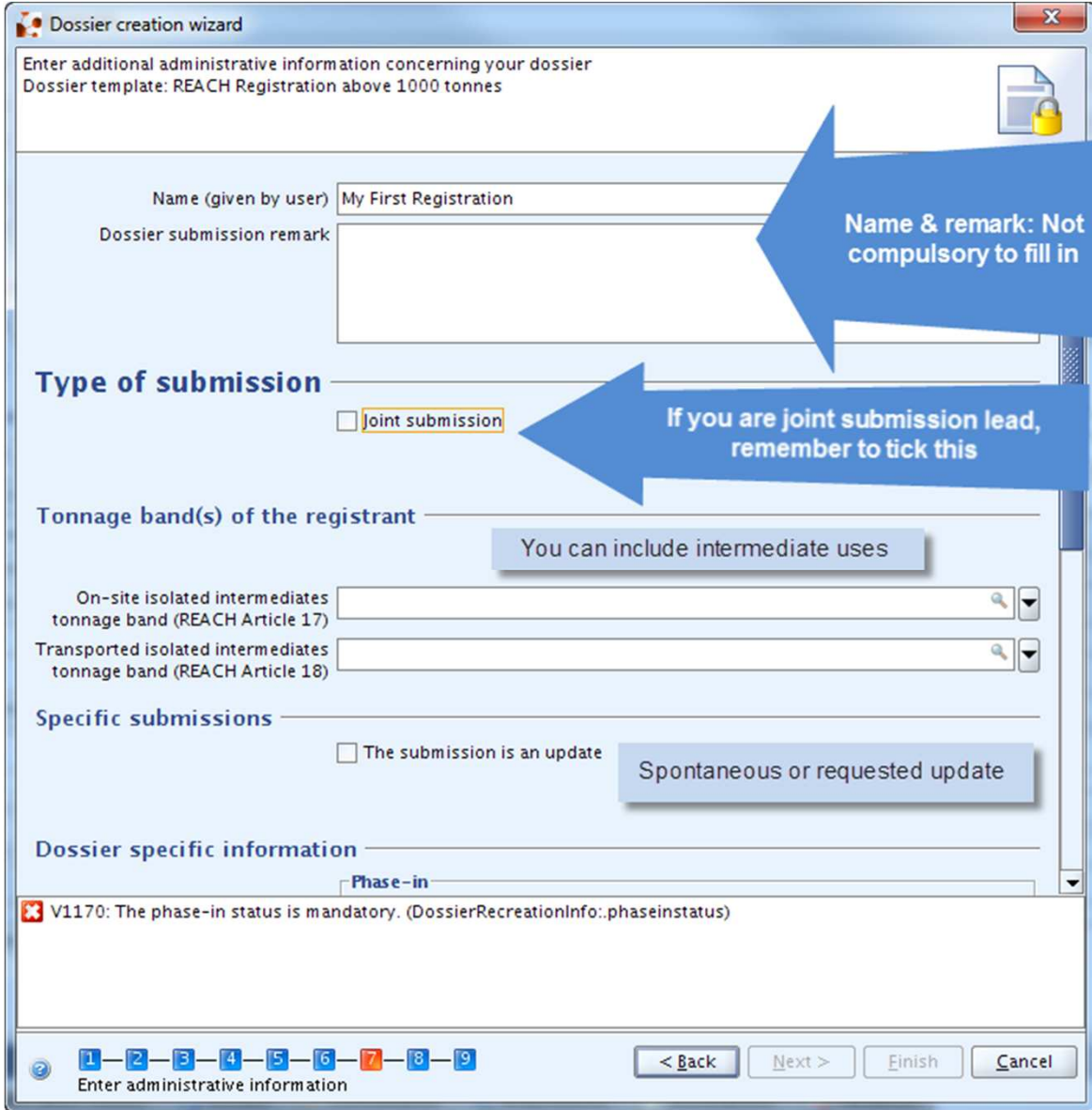
Any other

No regulatory purpose

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
Select data protection flags

< Back Next > Finish Cancel



Dossier creation wizard

Enter additional administrative information concerning your dossier
Dossier template: REACH Registration above 1000 tonnes

Name (given by user) My First Registration

Dossier submission remark

Type of submission

Joint submission

Tonnage band(s) of the registrant

You can include intermediate uses

On-site isolated intermediates tonnage band (REACH Article 17)

Transported isolated intermediates tonnage band (REACH Article 18)

Specific submissions

The submission is an update

Spontaneous or requested update

Dossier specific information

Phase-in

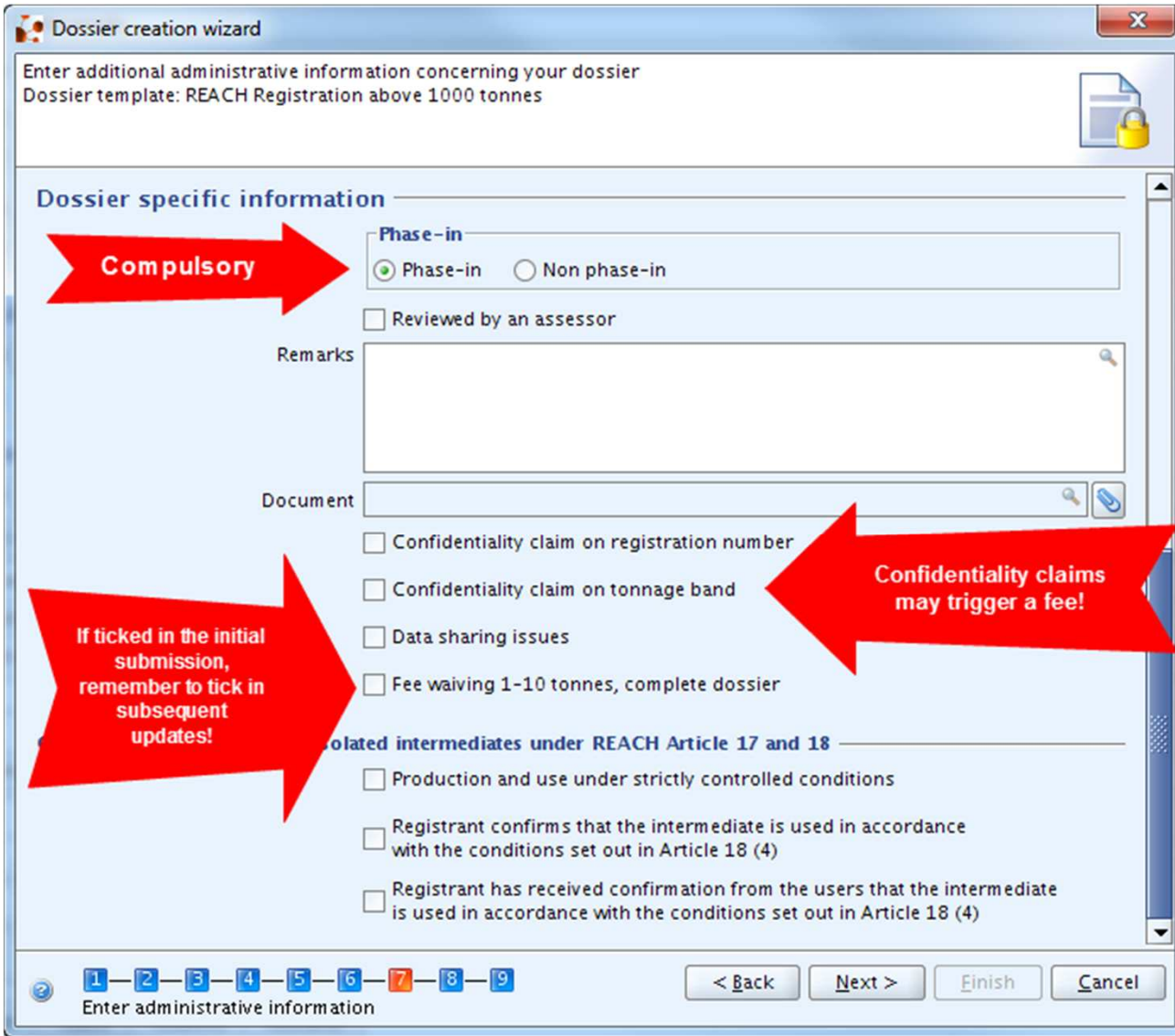
V1170: The phase-in status is mandatory. (DossierRecreationInfo:phaseinstatus)

1 2 3 4 5 6 7 8 9
Enter administrative information

< Back Next > Finish Cancel

Annotations:

- Name & remark: Not compulsory to fill in
- If you are joint submission lead, remember to tick this



Dossier creation wizard

Enter additional administrative information concerning your dossier
Dossier template: REACH Registration above 1000 tonnes

Dossier specific information

Compulsory → **Phase-in**
 Phase-in Non phase-in

Reviewed by an assessor

Remarks

Document

Confidentiality claim on registration number
 Confidentiality claim on tonnage band
 Data sharing issues
 Fee waiving 1-10 tonnes, complete dossier

If ticked in the initial submission, remember to tick in subsequent updates! →

Confidentiality claims may trigger a fee! ←

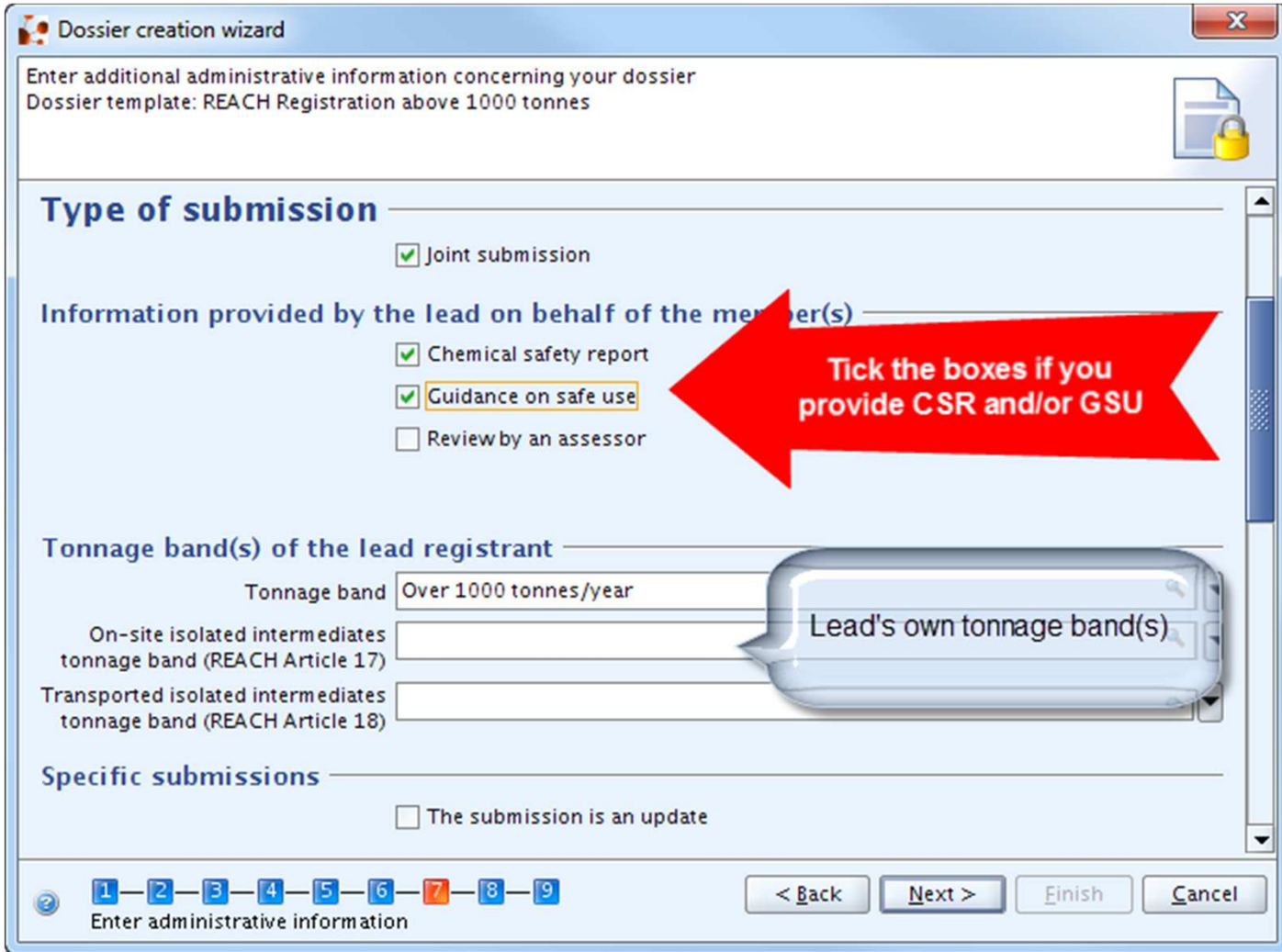
Related intermediates under REACH Article 17 and 18

Production and use under strictly controlled conditions
 Registrant confirms that the intermediate is used in accordance with the conditions set out in Article 18 (4)
 Registrant has received confirmation from the users that the intermediate is used in accordance with the conditions set out in Article 18 (4)

1 2 3 4 5 6 7 8 9
Enter administrative information

< Back Next > Finish Cancel

IUCLID Dossier header – Lead



Dossier creation wizard

Enter additional administrative information concerning your dossier
Dossier template: REACH Registration above 1000 tonnes

Type of submission

Joint submission

Information provided by the lead on behalf of the member(s)

Chemical safety report

Guidance on safe use

Review by an assessor

Tonnage band(s) of the lead registrant

Tonnage band: Over 1000 tonnes/year

On-site isolated intermediates tonnage band (REACH Article 17):

Transported isolated intermediates tonnage band (REACH Article 18):

Specific submissions

The submission is an update

1 2 3 4 5 6 7 8 9
Enter administrative information

< Back Next > Finish Cancel

IUCLID Dossier – plug-ins

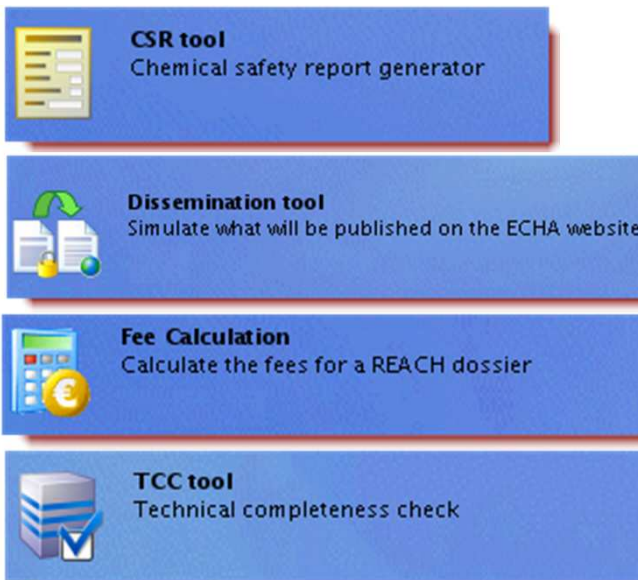


The screenshot shows the IUCLID 5 website interface. At the top, there is a navigation bar with the ECHA logo and three menu items: Home, IUCLID 5 Project, and User Info. Below the navigation bar, there is a list of links for various IUCLID 5 components:

- [Stand-alone version 5.4.1](#)
- [Distributed version 5.4.1](#)
- [CSR Plug-in](#)
- [Dissemination Plug-in](#)
- [Fee Calculation Plug-in](#)
- [Help System Plug-ins](#)
- [Query Plug-in](#)
- [Technical Completeness Check \(TCC\) Plug-in](#)

At the bottom of the screenshot, the URL echa.europa.eu is visible.

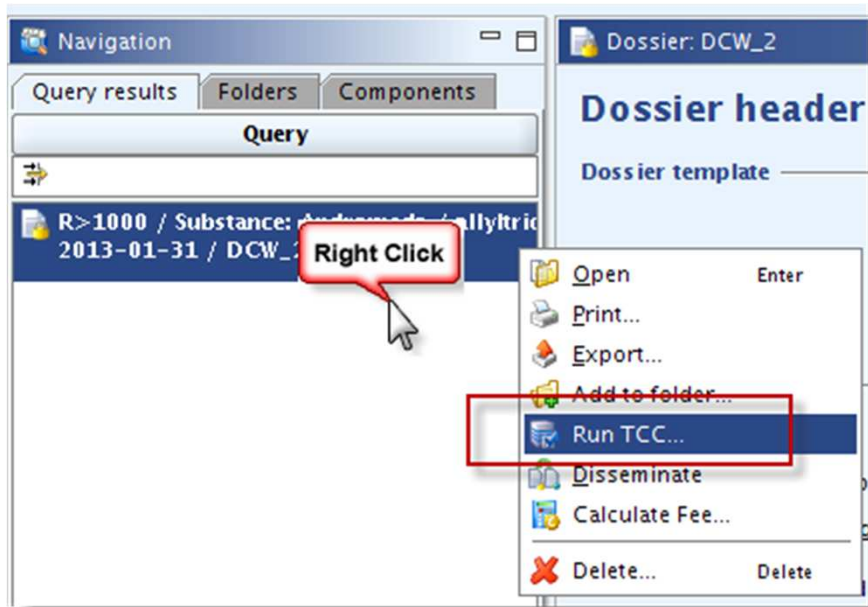
<http://iuclid.eu/>



A list of four IUCLID 5 plug-in tools, each with an icon and a description:

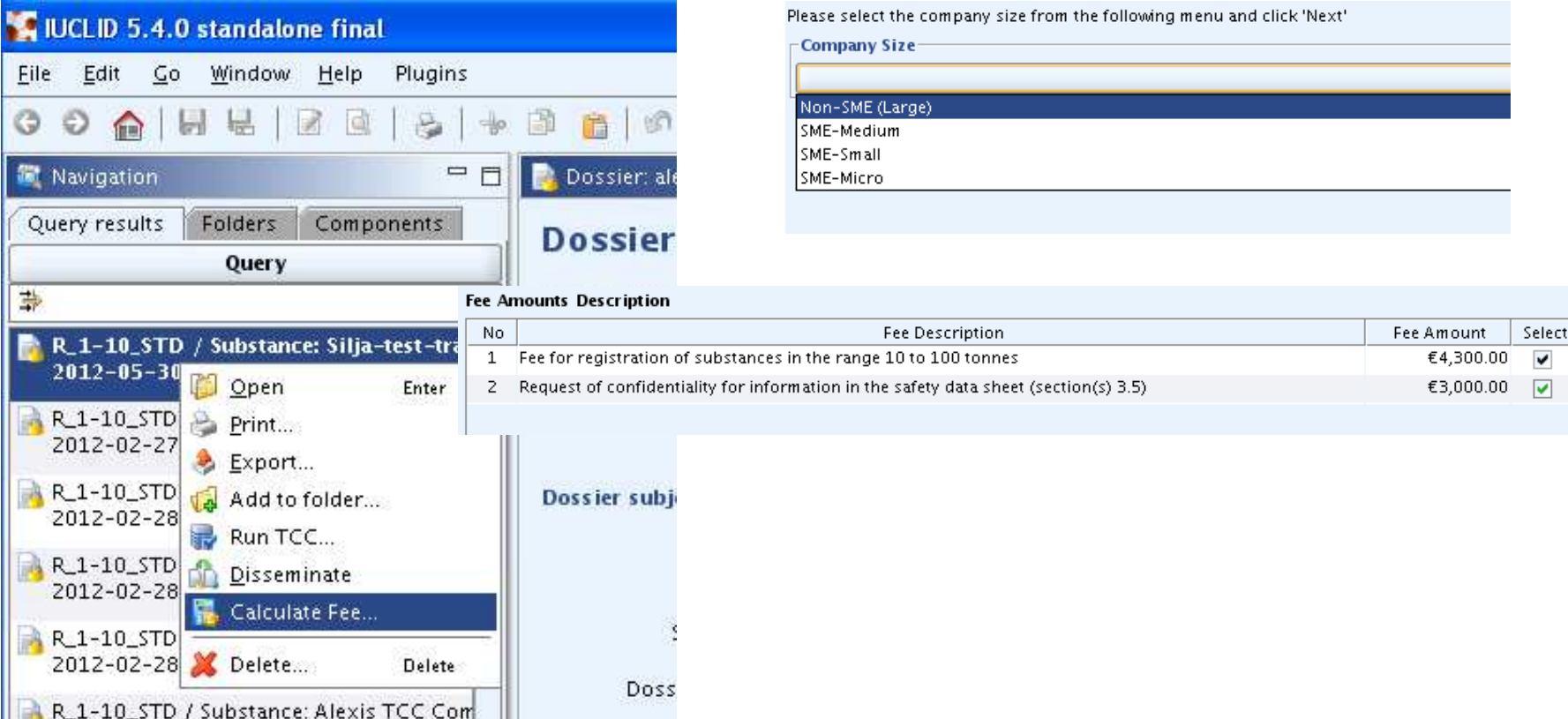
- CSR tool**
Chemical safety report generator
- Dissemination tool**
Simulate what will be published on the ECHA website
- Fee Calculation**
Calculate the fees for a REACH dossier
- TCC tool**
Technical completeness check

IUCLID Dossier – TCC plug-in



Checks
technical completeness
of
the **substance
dataset** and the
final **dossier**

IUCLID Dossier – Fee calculation plug-in



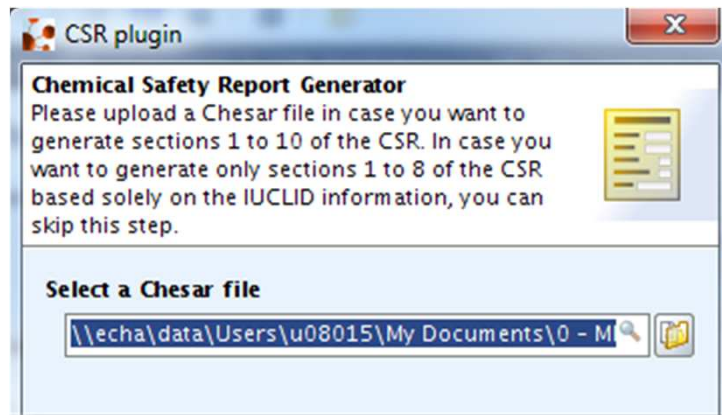
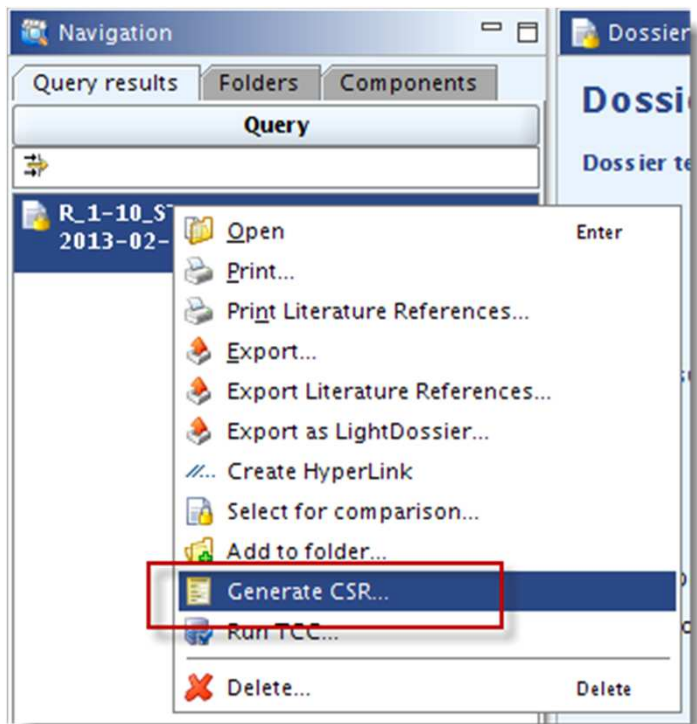
The screenshot shows the IUCLID 5.4.0 standalone final software interface. The 'Calculate Fee...' option is highlighted in the context menu for a dossier entry. A dialog box prompts the user to select a company size from a list: Non-SME (Large), SME-Medium, SME-Small, and SME-Micro.

Company Size

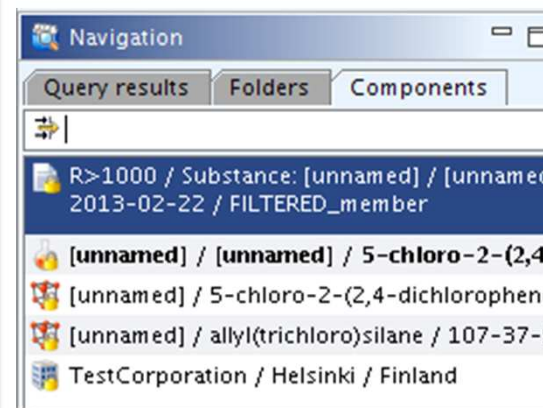
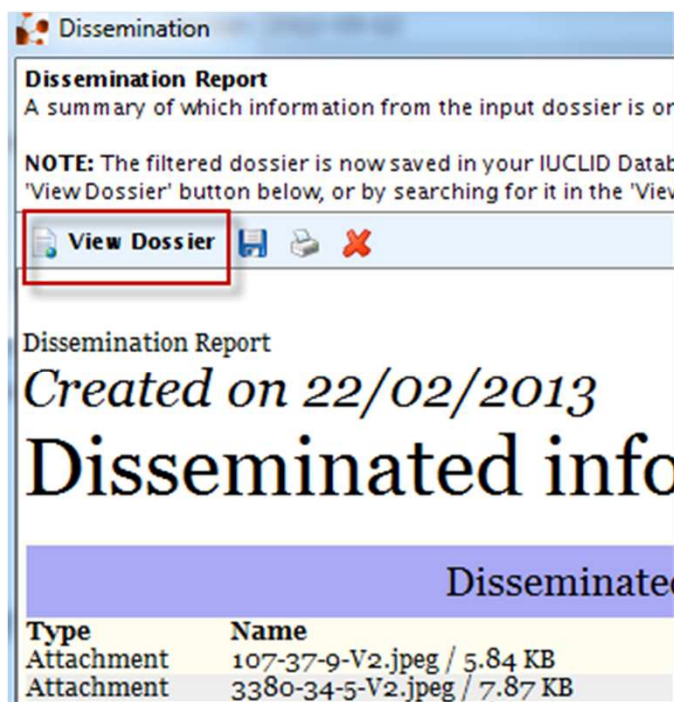
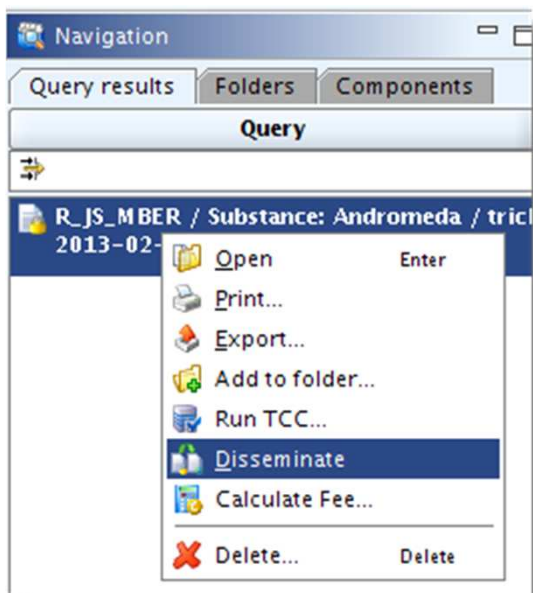
- Non-SME (Large)
- SME-Medium
- SME-Small
- SME-Micro

No	Fee Description	Fee Amount	Select
1	Fee for registration of substances in the range 10 to 100 tonnes	€4,300.00	<input checked="" type="checkbox"/>
2	Request of confidentiality for information in the safety data sheet (section(s) 3.5)	€3,000.00	<input checked="" type="checkbox"/>

IUCLID Dossier – CSR plug-in



IUCLID Dossier – Dissemination plug-in



Key messages:

- Export and submit only **dossiers**
- Use the TCC plug-in and the fee calculation plug-in
- Submit only TCC complete dossiers

Thank you for attending!