

# **Last minute advice on dossier preparation and submission**

Lead Registrant Webinar  
25<sup>th</sup> February 2013

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ECHA

# Agenda

**Short overview of the dossier creation**

**Business Rules**



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**Short overview of the dossier creation**

**Business Rules**



# Preparing and submitting dossiers

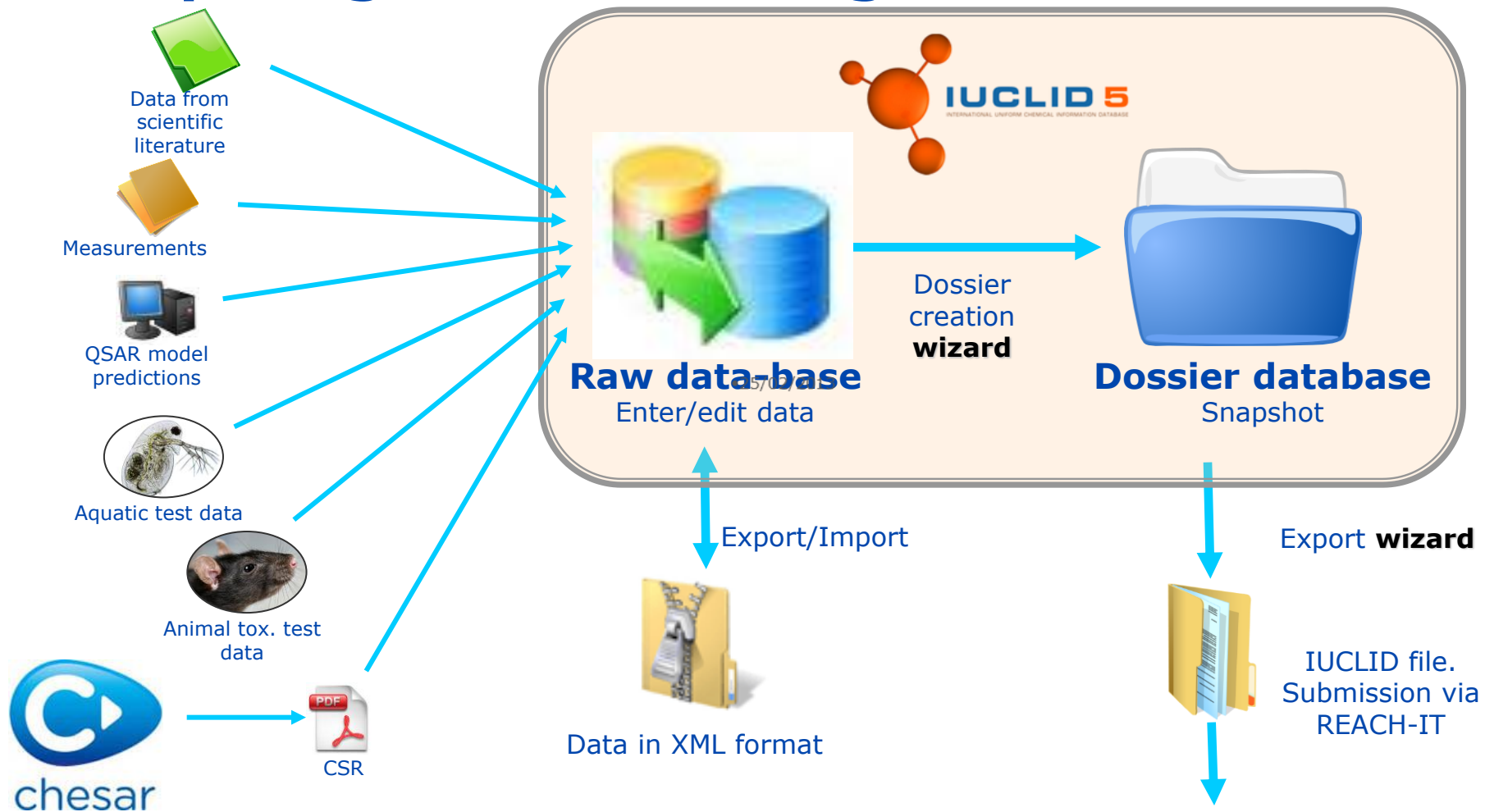
- Webinars:
  - General principles of dossier preparation and submission

[http://echa.europa.eu/web/guest/view-article/-/journal\\_content/2dff7a95-55f4-440d-82b6-a7b615d2b7af](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](http://echa.europa.eu/documents/10162/13654/ium6_dossier_submission_en.pdf)

# Preparing and submitting dossiers



# Dossier creation

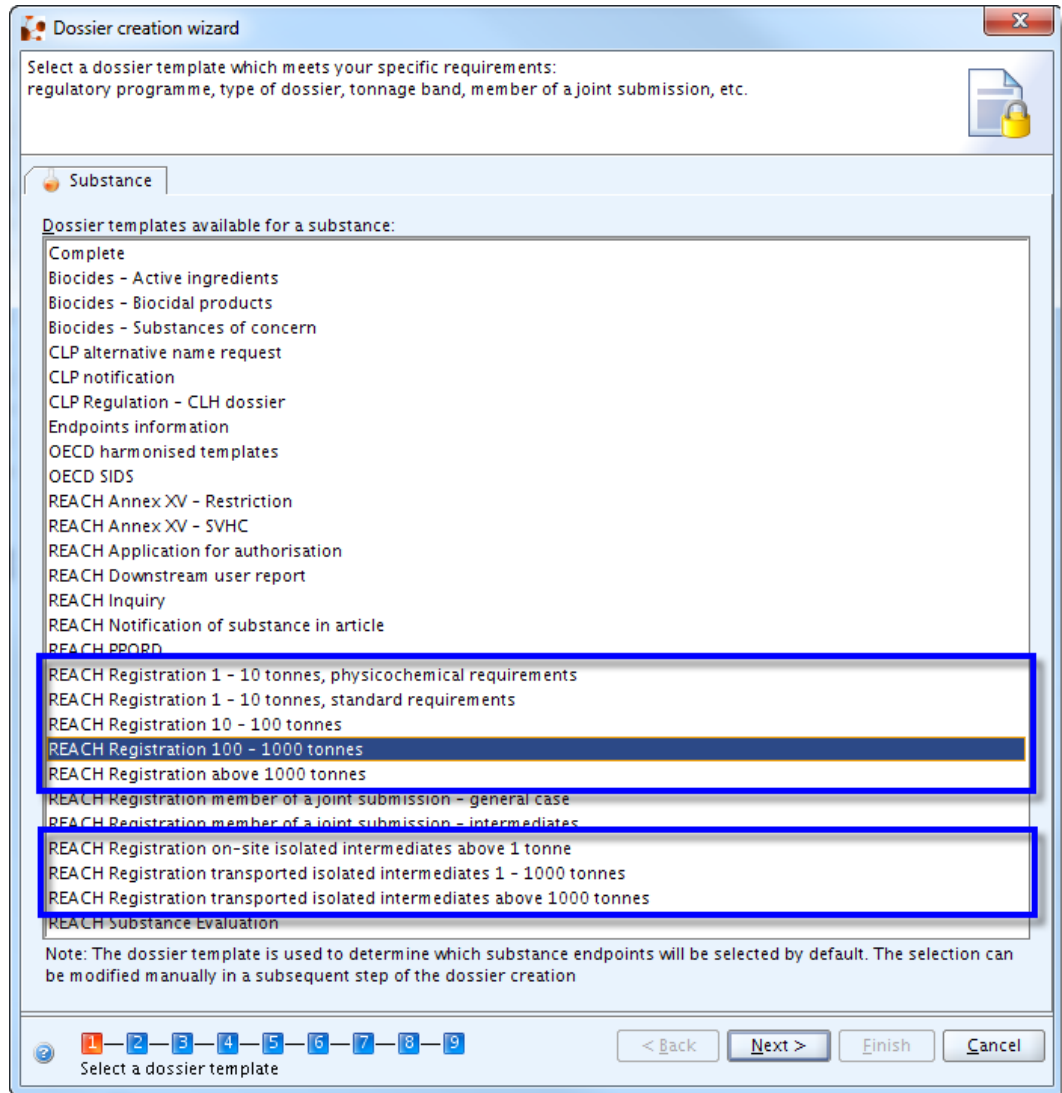
Raw data-base  
Enter/edit data



# Dossier creation wizard

## Step 1.

Define joint  
submissions  
tonnage band



The screenshot shows a window titled "Dossier creation wizard" with a close button in the top right corner. Below the title bar, there is a text area with the instruction: "Select a dossier template which meets your specific requirements: regulatory programme, type of dossier, tonnage band, member of a joint submission, etc." To the right of this text is a document icon with a yellow padlock. Below this is a tab labeled "Substance". Under the tab, the text reads "Dossier templates available for a substance:". A list of templates follows, with "REACH Registration 100 - 1000 tonnes" highlighted in blue. Below the list, there is a note: "Note: The dossier template is used to determine which substance endpoints will be selected by default. The selection can be modified manually in a subsequent step of the dossier creation". At the bottom, there is a progress bar with steps 1 through 9, where step 1 is active. To the right of the progress bar are buttons for "< Back", "Next >", "Finish", and "Cancel".

Dossier creation wizard

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

Substance

Dossier templates available for a substance:

- Complete
- Biocides - Active ingredients
- Biocides - Biocidal products
- Biocides - Substances of concern
- CLP alternative name request
- CLP notification
- CLP Regulation - CLH dossier
- Endpoints information
- OECD harmonised templates
- OECD SIDS
- REACH Annex XV - Restriction
- REACH Annex XV - SVHC
- REACH Application for authorisation
- REACH Downstream user report
- REACH Inquiry
- REACH Notification of substance in article
- REACH PPORD
- REACH Registration 1 - 10 tonnes, physicochemical requirements
- REACH Registration 1 - 10 tonnes, standard requirements
- REACH Registration 10 - 100 tonnes
- REACH Registration 100 - 1000 tonnes
- REACH Registration above 1000 tonnes
- REACH Registration member of a joint submission - general case
- REACH Registration member of a joint submission - intermediates
- REACH Registration on-site isolated intermediates above 1 tonne
- REACH Registration transported isolated intermediates 1 - 1000 tonnes
- REACH Registration transported isolated intermediates above 1000 tonnes
- REACH Substance Evaluation

Note: The dossier template is used to determine which substance endpoints will be selected by default. The selection can be modified manually in a subsequent step of the dossier creation

1 2 3 4 5 6 7 8 9

Select a dossier template

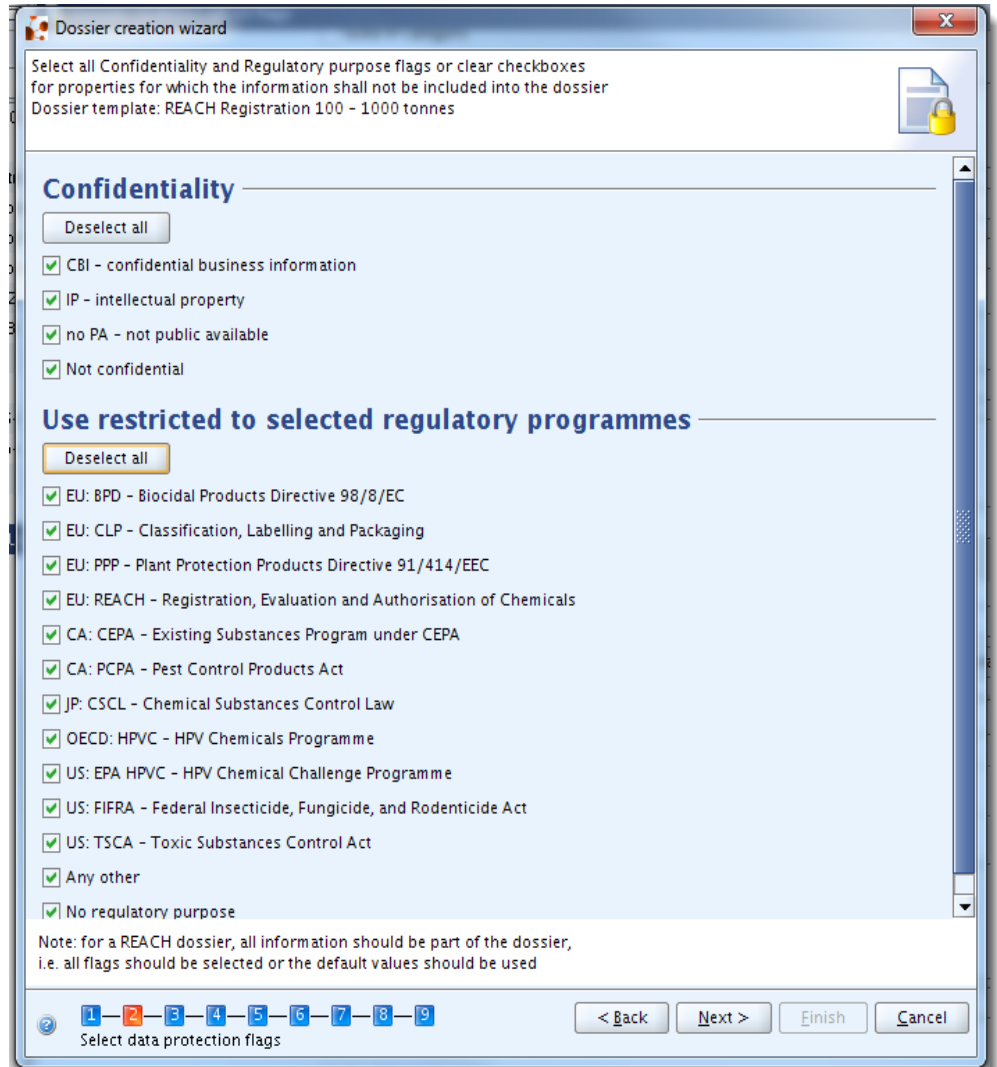
< Back Next > Finish Cancel



# Dossier creation wizard

## Step 2.

We suggest you to 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 100 - 1000 tonnes

**Confidentiality**

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

**Use restricted to selected regulatory programmes**

- 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

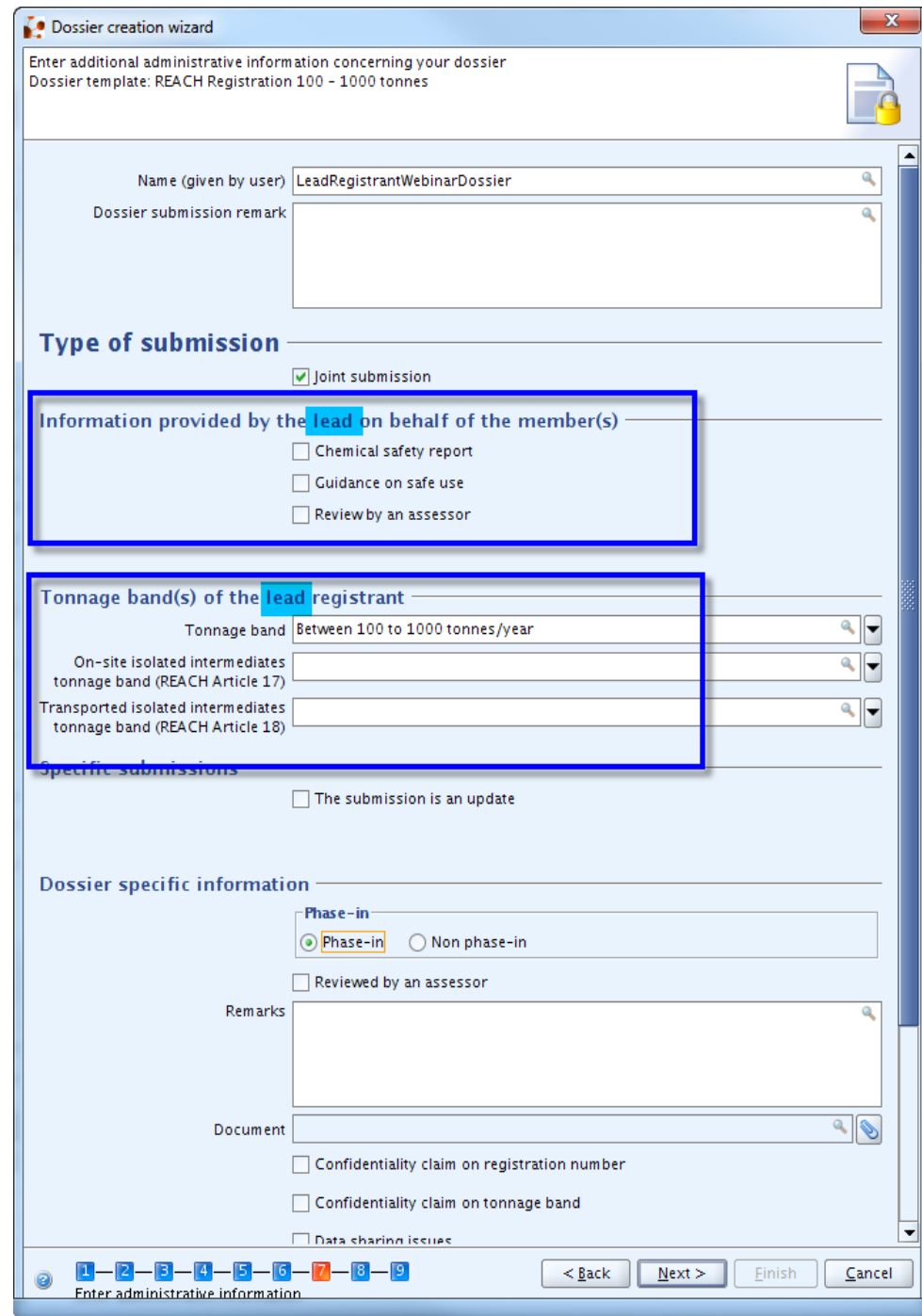
1 2 3 4 5 6 7 8 9  
Select data protection flags



# Dossier creation wizard

## Step 7.

Select the Dossier Header information



Dossier creation wizard

Enter additional administrative information concerning your dossier  
Dossier template: REACH Registration 100 - 1000 tonnes

Name (given by user)

Dossier submission remark:

**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:

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

Transported isolated intermediates tonnage band (REACH Article 18):

**Specific submissions**

The submission is an update

**Dossier specific information**

**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

1 2 3 4 5 6 7 8 9

Enter administrative information

< Back Next > Finish Cancel

# Verifying the Dossier Before Submission

Plug-ins to use:



TCC tool



Dissemination tool

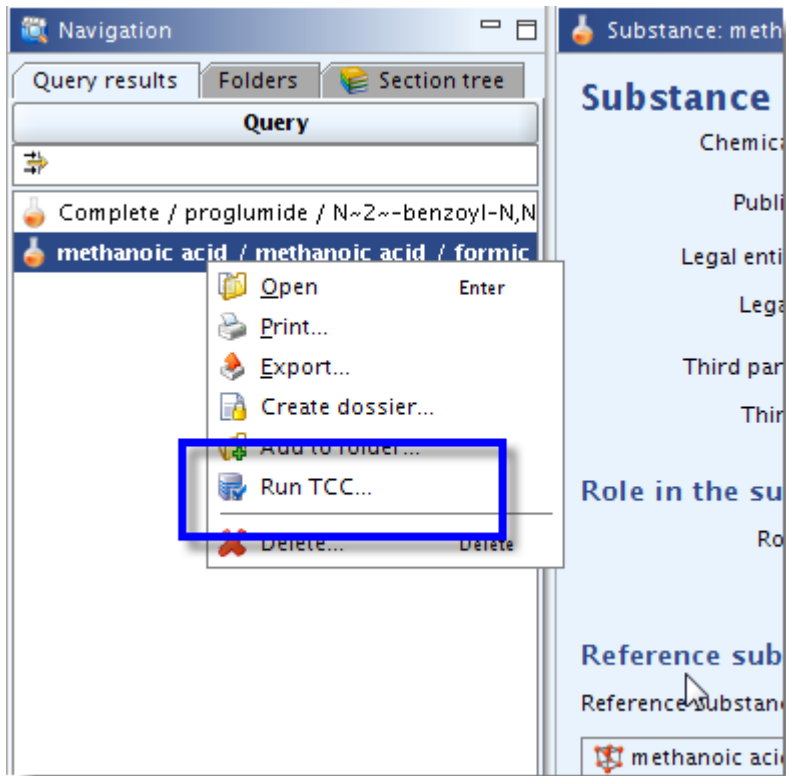


Fee Calculation

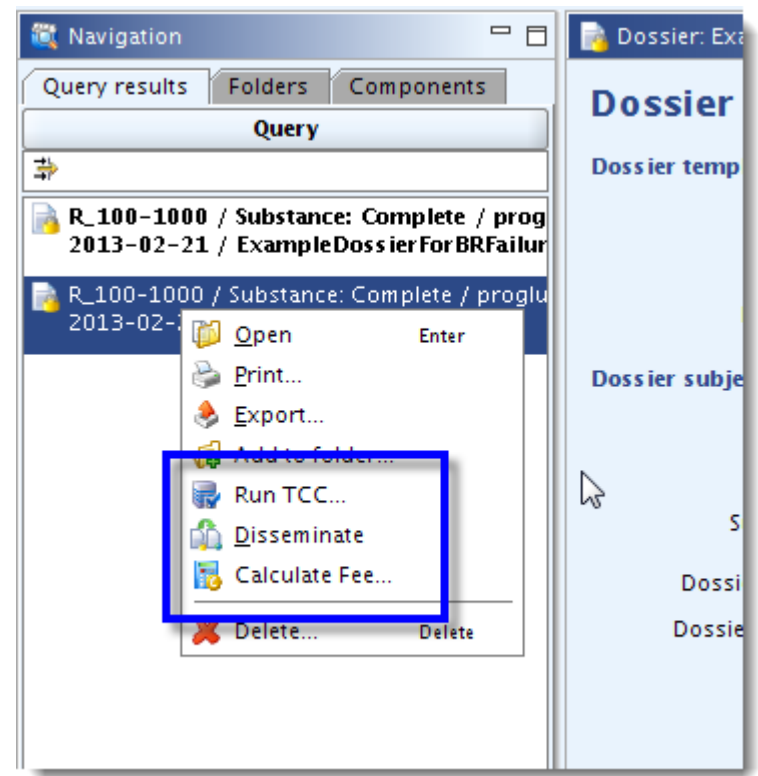
- Available for free from the IUCLID5 website
- Use the latest version

## How to run the Plug-ins:

In substance dataset:



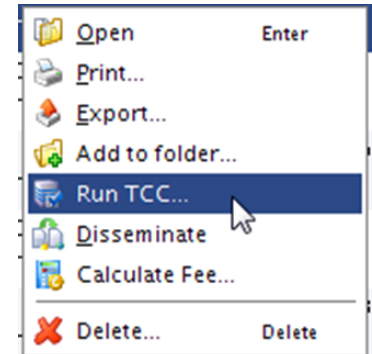
In final dossier:



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

## the TCC tool

- Checks most of the Business Rules
- Simulates 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 substance dataset or on dossier



# Run the TCC tool :

## Check that you have the latest version



# Run the TCC tool: Filter rules

Technical completeness check

Please ensure that you use the plug-in on the final dossier and correct all reported Technical Completeness Check and Business Rules failures before submitting your information to ECHA. Using the tool on the final dossier is vital for you to avoid failures.

Business Rules (2) Dossier Quality Assistant (10)

Technical Completeness Check (17)

Filter: Show all with type failure, warning

Section number	Section name	Document name	Failure description	Type
Section 2.1	GHS		Section 2.1 is invalid or missing	TCC failure
Section 2.1	GHS, (2), Specific target organ toxicity - single (1)		Neither a 'Hazard category' and a 'Hazard statement' nor a 'Reason for no classification' is given for 'Specific target organ toxicity - single' in section GHS. If a classification is given, the 'Affected organs' must be indicated.	TCC failure
Section 2.1	GHS, (3), Specific target organ toxicity - single (1)		Neither a 'Hazard category' and a 'Hazard statement' nor a 'Reason for no classification' is given for 'Specific target organ toxicity - single' in section GHS. If a classification is given, the 'Affected organs' must be indicated.	TCC failure
Section 2.1	GHS, (4), Specific target organ toxicity - single (1)		Neither a 'Hazard category' and a 'Hazard statement' nor a 'Reason for no classification' is given for 'Specific target organ toxicity - single' in section GHS. If a classification is given, the 'Affected organs' must be indicated.	TCC failure

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

Results

< Back Next > Finish Cancel

# Run the TCC tool: 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:

The screenshot shows the 'Technical completeness check' window. At the top, there is a message: 'Please ensure that you use the plug-in on the final dossier and correct all reported Technical Completeness Check and Business Rules failures before submitting your information to ECHA. Using the tool on the final dossier is vital for you to avoid failures.' Below this, the 'Business Rules' section is active, showing 'Technical Completeness Check' and 'Dossier Quality Assistant (1/0)'. A filter is set to 'Show all' and 'with type' is set to 'failure, warning'. The main table displays two rows of results:

Section number	Section name	Document name	Failure description	Type
Rules for lead registration dossier between 100 and 1000 tonnes			Your dossier/substance dataset is considered as complete for the indicated tonnage band. However, please note that the completeness check performed by ECHA might include additional checks as for instance the relationship with other dossiers (e.g. lead versus member). These additional checks could potentially lead to different conclusions from those indicated by this tool. The use of the TCC tool is without prejudice to the obligation to submit a dossier that fulfils all relevant legal requirements.	TCC disclaimer
			No BR failures were detected by the plug-in. Please note that some of the business rules can only be checked at dossier level. Also note that due to technical reasons the BR check performed by the plug-in does not cover all business rules checked at ECHA.	BR disclaimer

At the bottom of the window, the version information is displayed: 'TCC engine version: 7.00', 'Business rules version: 2.2.10', and 'Completeness rules version: 2.2.8'. Navigation buttons include '< Back', 'Next >', 'Finish', and 'Cancel'. A 'Results' tab is visible at the bottom left.



# Run the TCC tool:

## New feature: Dossier Quality Assistant

Technical completeness check

The Dossier Quality Assistant helps registrants to detect technical inconsistencies in the information provided in their dossiers. These inconsistencies are reported as Quality rules and Substance Identity rules. Please note that this tool does not carry out a full assessment of the adequacy of the information provided.

Business Rules  
Technical Completeness Check **Dossier Quality Assistant (16)**

Filter: Show all with type failure, warning

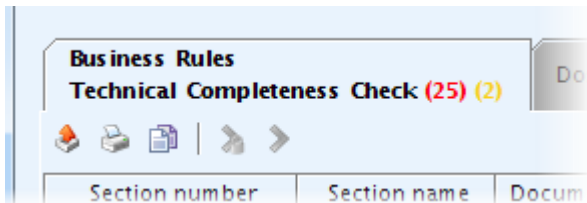
Section number	Section name	Document name	Failure description	Type
			Quality concerns have been detected for this substance dataset / dossier. You are advised to revise the sections corresponding to the warning messages as they may trigger follow-up actions from ECHA.	Dossier Quality disclaimer
			While the quality warnings have been designed to assist the user in detecting inconsistencies in the information provided, there may be special circumstances in which some of the warnings can be ignored. The use of this tool is without prejudice to the expert assessment carried out by ECHA to establish the adequacy of the information required under Article 10, 17 and 18 of the REACH Regulation.	
Section 1.4	Analytical information		Warning in Substance Identity Rule SID024	Substance Identity warning
Section 1.4	Analytical information		Section 1.4: For each substance, the analytical information must be sufficient to enable each substance to be identified and quantified.	Substance Identity warning

Dossier Quality rules version: 1.0.0 Substance identity rules version: 1.2.2

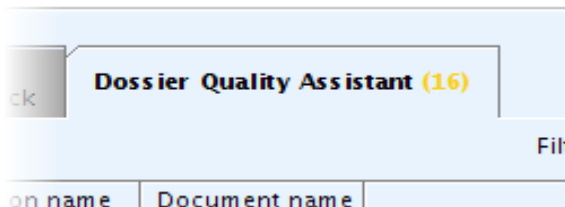
Results

< Back Next > Finish Cancel

# The TCC tool



- **BR failure** → Dossier fails BR in REACH-IT
- **TCC failure** → Dossier fails TCC in REACH-IT
- **BR warning** is not an indication of that your dossier will fail the Business Rules, but it suggests that some information that should normally be in your registration dossier is missing.
- **TCC warning** is not an indication of that your dossier will fail the Technical Completeness Check, but it suggests that some information that should normally be in your registration dossier is missing.
- **BR disclaimer** no BR failures found
- **TCC disclaimer** no 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 plugin

**Fee Calculation Assistant**

**Dossier Template:** REACH Registration 100 - 1000 tonnes  
**Dossier Subject:** Complete / diazepam / 7-chloro-1-methyl-5-phenyl-1,3-dihydro-2H-1,4-benzodiazepin-2-one / 439-14-5 / S Export and Import / Stockholm / Sweden

**Selected Values**

**Company Size:** SME-Medium  
**Update info:** N/A  
**Dangerous Substance:** N/A

**Fee Amounts Description (Joint Submission)**









No	Fee Description	Fee Amount	Select
1	Fee for registration of substances in the range 100 to 1000 tonnes	€6,038.00	<input checked="" type="checkbox"/>
2	Fee for registration of on-site intermediates	€840.00	<input checked="" type="checkbox"/>
3	Request of confidentiality for relevant tonnage band (dossier header)	€788.00	<input checked="" type="checkbox"/>

**Total Amount:** €7,666.00

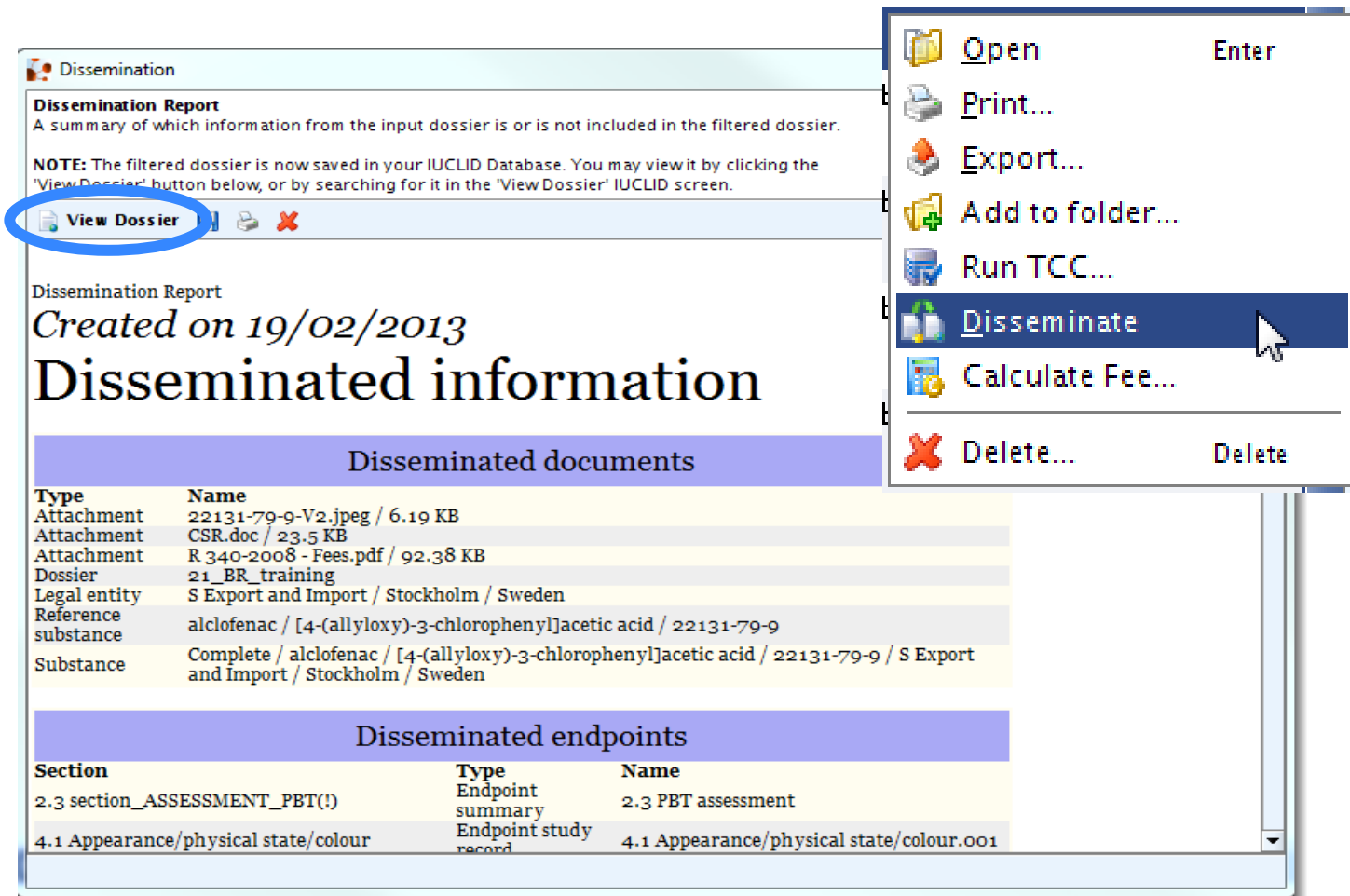
Disclaimer: Please note that this plug-in provides only preliminary estimates of the amounts charged in connection with registrations and PPORD notifications according to Article 74 of Regulation (EC) No 1907/2006 and Regulation (EC) No 340/2008. The amount estimated by this plug-in takes into account only the fees specified in Section 1 of the plug-in User Manual as they were laid down at the time of the publication of this plug-in. ECHA shall not be held liable for any differences between the estimated amount and the amount charged in the actual invoice.

1 2 3 4  
Fee Amounts

< Back Next > Finish Cancel

-  **O**pen Enter
-  **P**rint...
-  **E**xport...
-  **A**dd to folder...
-  **R**un TCC...
-  **D**isseminate
-  **C**alculate Fee... ↩
-  **D**elete... Delete



# Run the Dissemination tool



**Dissemination**

**Dissemination Report**  
A summary of which information from the input dossier is or is not included in the filtered dossier.

**NOTE:** The filtered dossier is now saved in your IUCLID Database. You may view it by clicking the 'View Dossier' button below, or by searching for it in the 'View Dossier' IUCLID screen.

[View Dossier](#)  

Dissemination Report  
*Created on 19/02/2013*  
**Disseminated information**

**Disseminated documents**

Type	Name
Attachment	22131-79-9-V2.jpeg / 6.19 KB
Attachment	CSR.doc / 23.5 KB
Attachment	R 340-2008 - Fees.pdf / 92.38 KB
Dossier	21_BR_training
Legal entity	S Export and Import / Stockholm / Sweden
Reference substance	alclofenac / [4-(allyloxy)-3-chlorophenyl]acetic acid / 22131-79-9
Substance	Complete / alclofenac / [4-(allyloxy)-3-chlorophenyl]acetic acid / 22131-79-9 / S Export and Import / Stockholm / Sweden

**Disseminated endpoints**

Section	Type	Name
2.3 section_ASSESSMENT_PBT(!)	Endpoint summary	2.3 PBT assessment
4.1 Appearance/physical state/colour	Endpoint study record	4.1 Appearance/physical state/colour.001

Context menu options:

- Open (Enter)
- Print...
- Export...
- Add to folder...
- Run TCC...
- Disseminate** (highlighted)
- Calculate Fee...
- Delete... (Delete)

# Dossier export

Dossier database  
Snapshot

The screenshot displays the IUCLID 5 Test version 5.2.1.C interface. On the left, a navigation pane shows a list of dossiers under 'Query results' and 'Components'. A context menu is open over one of the entries, listing actions: Open, Print..., Export..., Generate CSR, Run TCC..., Disseminate, and Delete... The 'Export...' option is highlighted. The main window shows the 'Dossier: Training1' header form with the following details:

- Dossier header**
- Dossier template: Name: REACH Registration above 1000 tonnes, Version: 2010-02-10, Name (given by user): Training1
- Dossier subject**: Name: Complete / Formic acid / ,jkh / 50-00-0 / ECHA / Hels, Public name: Acid formic, Submitting legal entity: Aho oy / Espoo / Finland, Dossier creation date/time: 2010-04-14 09:01:16 EEST, Dossier submission remark: (empty)
- Type of submission**: On-site isolated intermediates tonnage band (checked), Joint submission (unchecked)

Below the header form is the 'Information' section with tabs for Consultation, Attachments, Annotations, and Validation. The 'Information' tab is active, showing:
 

- Type: Dossier
- UUID: IUCS-39bf77ce-3a13-4cbc-9ac1-da3d1df17ece
- Dossier UUID: IUCS-39bf77ce-3a13-4cbc-9ac1-da3d1df17ece
- Options: Sealed (checked), Copy protected (unchecked), Subset of original (unchecked)

 The bottom status bar shows 'Assign a legal entity to the current user' and the user 'SuperUser'.

# Agenda

**Short overview of the dossier creation**

**Business Rules**



# What happens after dossier submission

This step **must** be successfully completed before the deadline.

**Earlier submission recommended!**

Virus check  
File format validation  
XML Structure  
**BUSINESS RULES (BR)**

Technical Completeness Check + Invoicing  
Overall Completeness Check  
Registration number is assigned  
Confidentiality Claim Assessment  
Dissemination

These steps can take place after the 31th of May deadline

Evaluation



# What happens in REACH-IT

- Details
- Submission Report
- Status of processes
- Content
- Accounting
- Annotations
- Comments

## Passed Tasks

No.	Task	Remark	Result
1.	Virus check	-	Succeeded
2.	File format validation	-	Succeeded
3.	Check XML structure	-	Succeeded
4.	Enforce Rules	-	Succeeded
5.	Store Dossier	-	Succeeded
6.	Create Substance Identity	-	Succeeded
7.	Assign MSCAs	-	Succeeded
8.	Technical Completeness Check	-	Started
9.	Pay Submission Fee	-	Started
10.	Overall Completeness Check	-	Not Performed Yet
11.	Issue Reference Number	-	Not Performed Yet
12.	End of Pipeline Activities	-	Not Performed Yet
13.	Data Dissemination	-	Not Performed Yet
14.	Trigger WorkFlow	-	Not Performed Yet

Labeling

Message box [View my messages](#)

Downstream user

The list below displays the internal messages that were sent to you the last 30 days. To view all internal messages, click on [Message box folder](#) | [User folder](#) | [Organisation folder](#) | [Role folder](#) | [Deleted messages](#)

Select All | Select None

Select	Details	Read	Subject	Creation Date
<input type="checkbox"/>	<a href="#">Show</a>	Yes	Business Rules Check passed	10/01/2013 22:20
<input type="checkbox"/>	<a href="#">Show</a>	Yes	File under examination (LN143899-08) - Registration (reg.)	10/01/2013 22:20

[Delete](#)
[Move to...](#)
[Message box folder](#) ▼

## Business Rules Verification (BR)

- Administrative check
- Checked in REACH-IT
  - Format: verification of information
  - Administrative: certain information must be present in the dossier to be able to handle it
- If passed, dossier is accepted for processing

# Most common Business Rule failures in initial dossiers

Business Rule	Short description of the rule
1 <b>BR131</b>	The <b>legal entity</b> indicated in the <b>dossier header</b> and/or in section 1.1 Substance identification of your IUCLID 5 dossier <b>is different from the one used to submit the dossier in REACH-IT.</b>
2 <b>BR027</b>	In case the <b>JS name indicated in REACH IT is not for the correct substance ID</b> , error message is 'The substance identity in your dossier does not correspond to the information available in the joint submission you have indicated in REACH IT during the submission of this dossier.'  In <b>case no JS was indicated in REACH IT but the company is part of a JS for the same substance</b> , the error message is 'The system has detected that you are part of a Joint Submission for this substance. You have to indicate the Joint Submission name during the submission in REACH IT'.
3 <b>BR024</b>	The <b>IUCLID 5 template</b> used in your dossier <b>is not valid for this submission type.</b>

- Manual: Data Submission Manual 4 – How to Pass Business Rule Verification

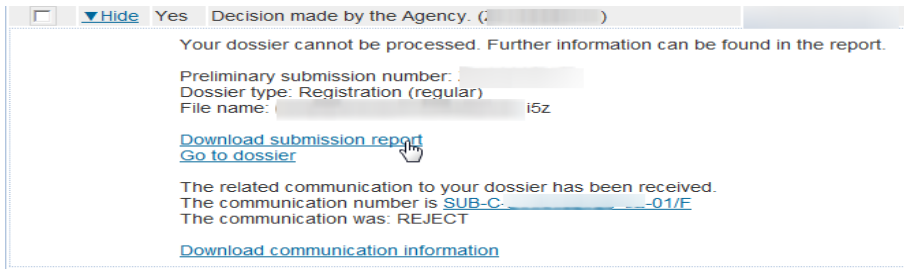
<http://echa.europa.eu/web/guest/support/dossier-submission-tools/reach-it/data-submission-industry-user-manuals>

- Webinar: Registration process I: Business Rules – What they are and how to pass them

[http://echa.europa.eu/web/guest/view-article/-/journal\\_content/ac5c7739-a57d-41a3-9163-be762eafeab0](http://echa.europa.eu/web/guest/view-article/-/journal_content/ac5c7739-a57d-41a3-9163-be762eafeab0)

# What If I Have Failed Business Rules?

- Communication is sent to REACH-IT mailbox
  - Check submission report



Submission Report - [redacted] Downloaded on 21/02/2013

Passed Tasks


No.	Task	Remark	Result
1.	Virus check	-	Succeeded
2.	File format validation	-	Succeeded
3.	Check XML structure	-	Succeeded
4.	Enforce Rules	-	Failed

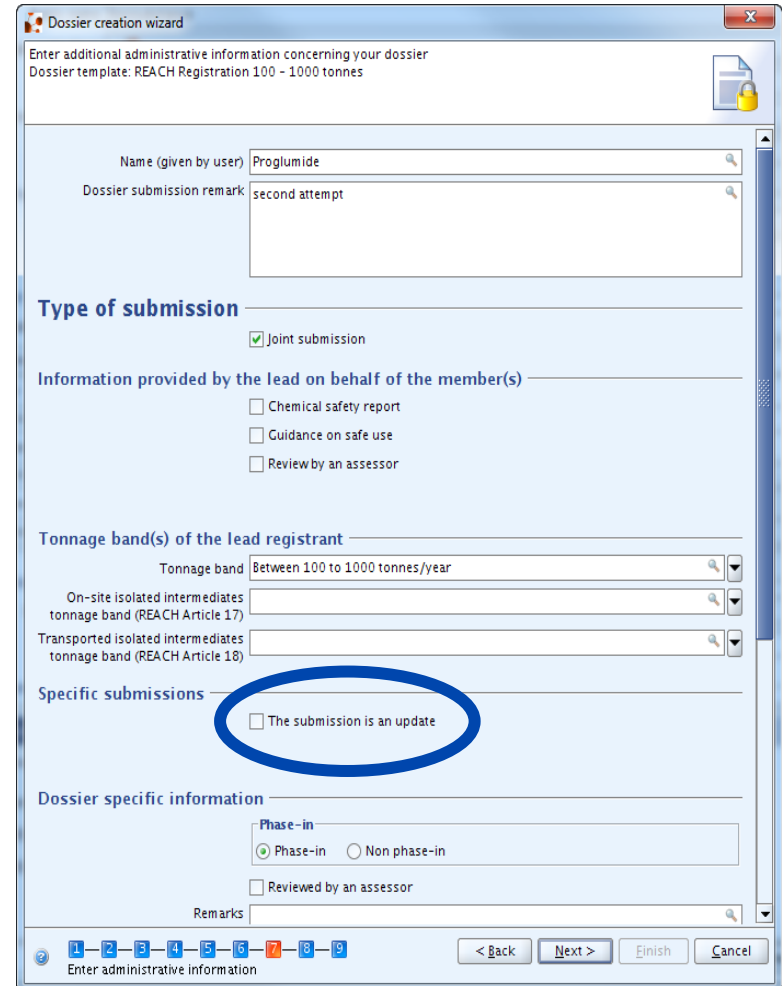
Joint Submission

Rule Name: BR101	Failed
Rule Level: Mandatory	Failed
Rule Result: Not Satisfied	Failed
Rule Message: There is an inconsistency concerning the Joint Submission status of your submission. If you indicated that your submission was part of a JS in REACH-IT, you must indicate this also in the IUCLID dossier header. If you have not joined a JS in REACH-IT, you cannot submit a member dossier for this substance.	Failed

- Don't panic!
  - Can resubmit as many times, as needed
  - No fee is charged related to these BR failures
  - No deadline for resubmission (except REACH deadline 31th of May 2013 still applies for 100-1000t/year dossiers)

# If your **initial** dossier fails in Business Rules then...

- Identify the failure. Correct it.  
Dossier can not be modified, editing is only allowed in 'substance dataset' mode. 
- Create the new dossier. Do not tick 'The submission is an update' box.
- Check your new dossier with the TCC tool!



## Key Messages

- Run the TCC-tool in the dossier
- Business Rules step must pass BEFORE the deadline
- Lead dossiers Business Rules have to be passed, before members can proceed with their submissions
- Contact ECHA Helpdesk



**Thank you!**

