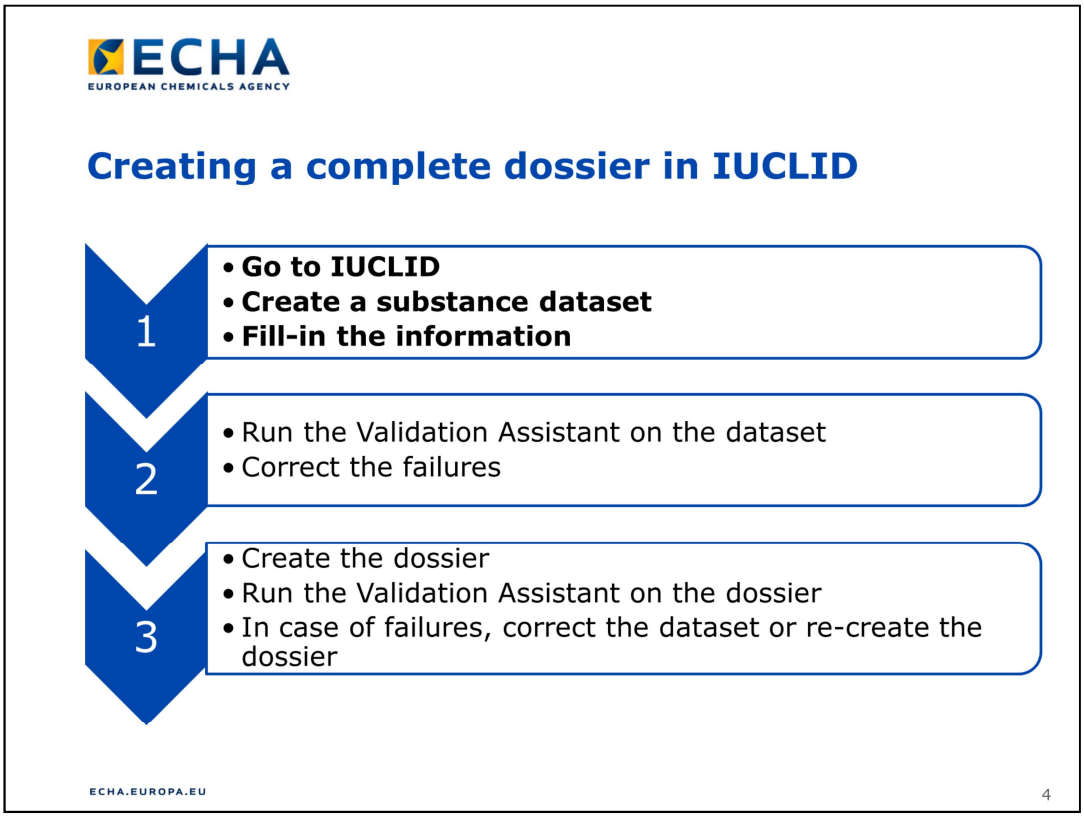
REACH IT tools training:

- IUCLID 6
- Completeness Check
- Regulatory processing

Agenda

- IUCLID 6 functionalities
- Validation assistant
- Dossier creation
- Regulatory processing
- Summary
- Support and guidance

IUCLID 6 functionalities



Creating a complete dossier in IUCLID

1.

- Go to IUCLID
- Create a substance dataset
- Fill-in the information

2.

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

3.

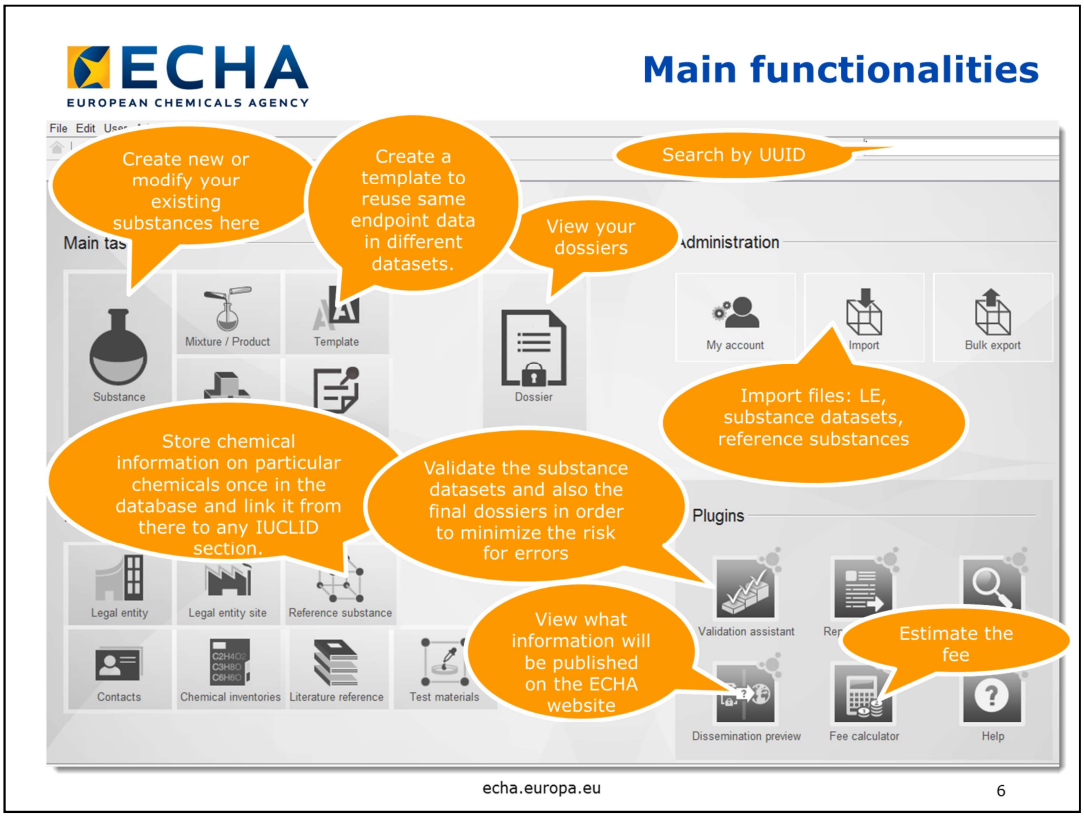
- Create the dossier
- Run the Validation Assistant on the dossier
- In case of failures, correct the dataset or re-create the dossier

Download

- Sign in and download the application

Support

- Download data, e.g. reference substances;
- FAQ regarding installation
- Migration from IUCLID5 to IUCLID6
- Technical manuals
- Etc.



Main functionalities

Free-text field in the top right corner

- Search by UUID

Substance

- Create new or modify your existing substances here

Template

- Create a template to reuse same endpoint data in different datasets

Dossier

- View your dossiers

Import

- Import files
  - LE
  - substance datasets
  - reference substances

Reference substance

- Store chemical information on particular chemicals once in the database and link it from there to any IUCLID section.

Validation assistant

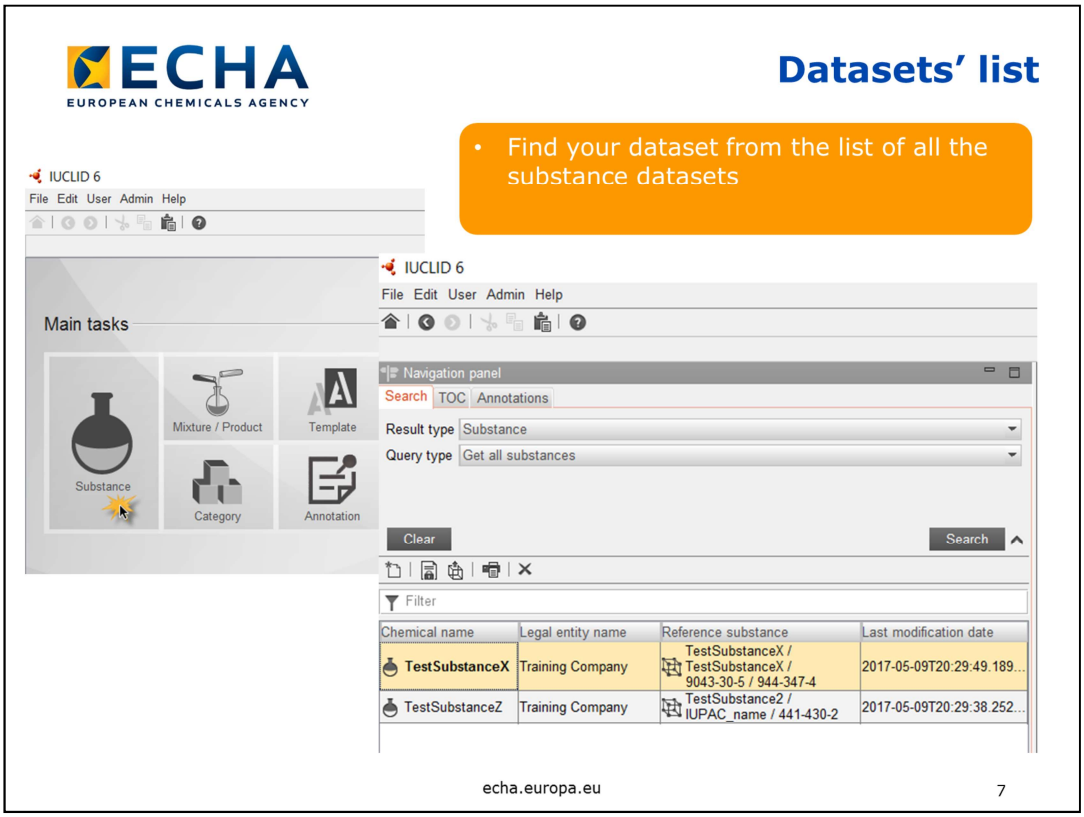
- Validate the substance datasets and also the final dossiers in order to minimize the risk for errors

Dissemination preview

- View what information will be published on the ECHA website

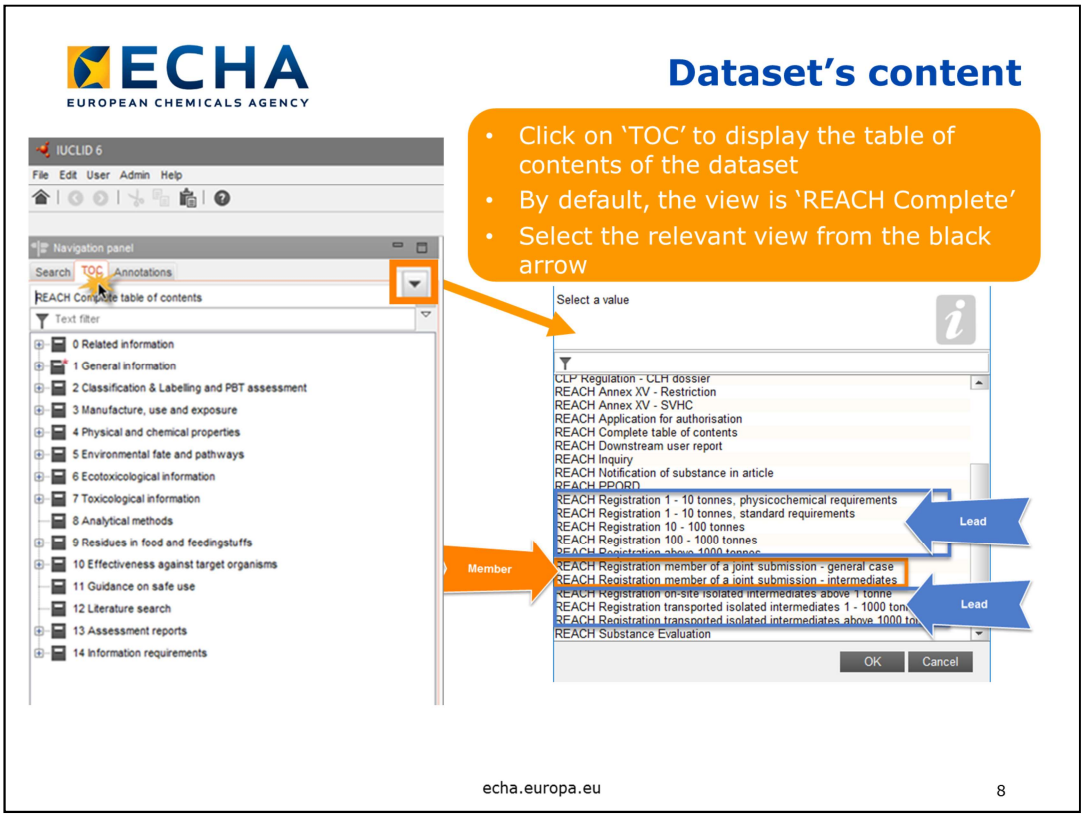
Fee calculator

- Estimate the fee



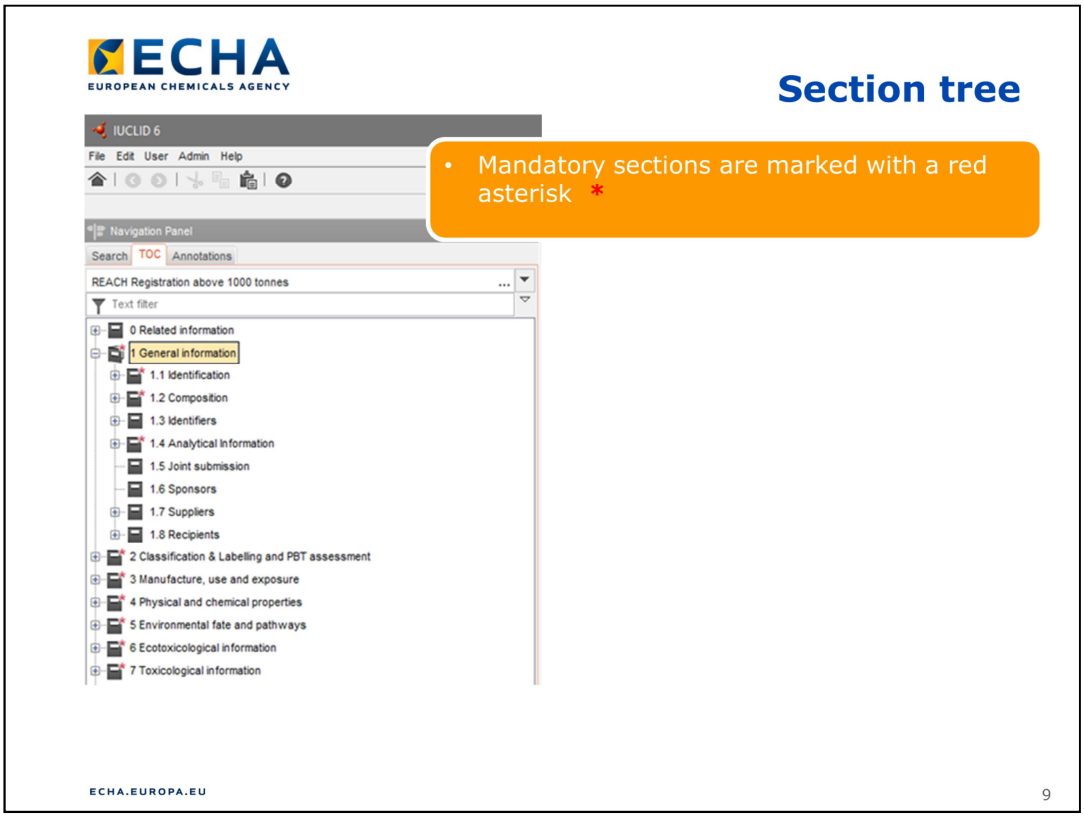
Datasets' list

- Find your dataset from the list of all the substance datasets



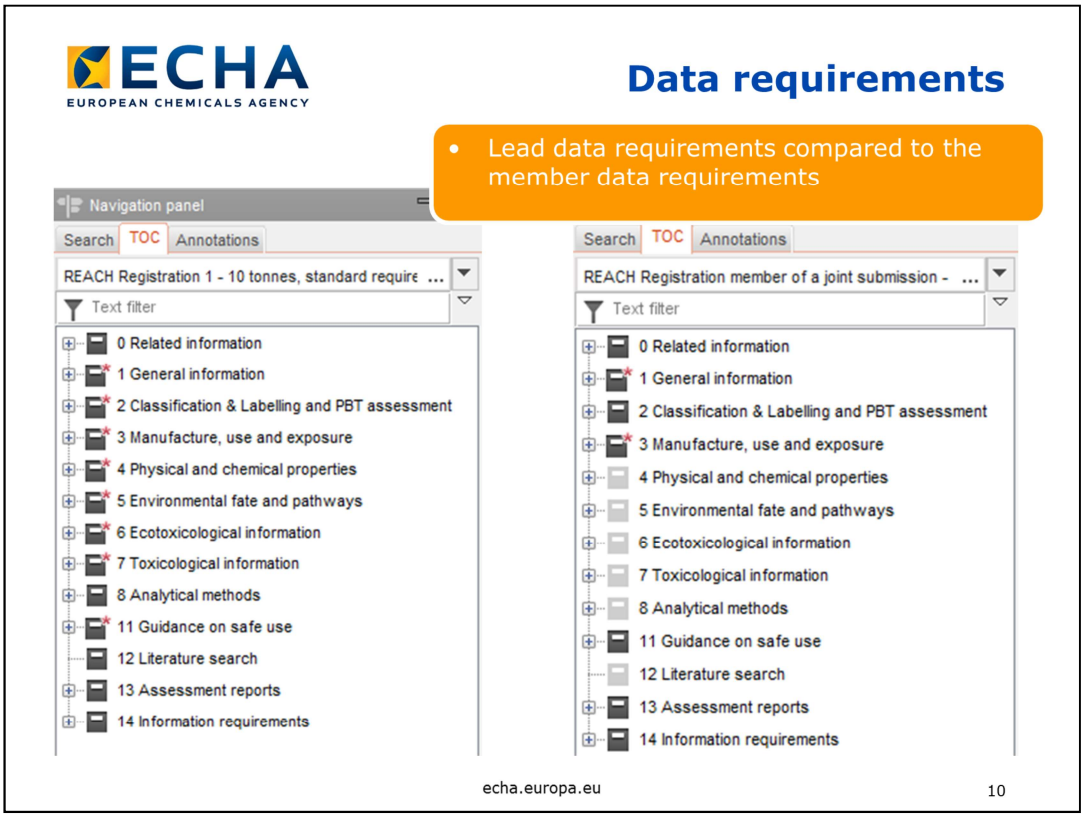
Dataset's content

- Click on 'TOC' to display the table of contents of the dataset
- By default, the view is 'REACH Complete'
- Select the relevant view from the black arrow
- Blue boxes indicate the options for the lead registrant
- Orange box shows the options for member registrant



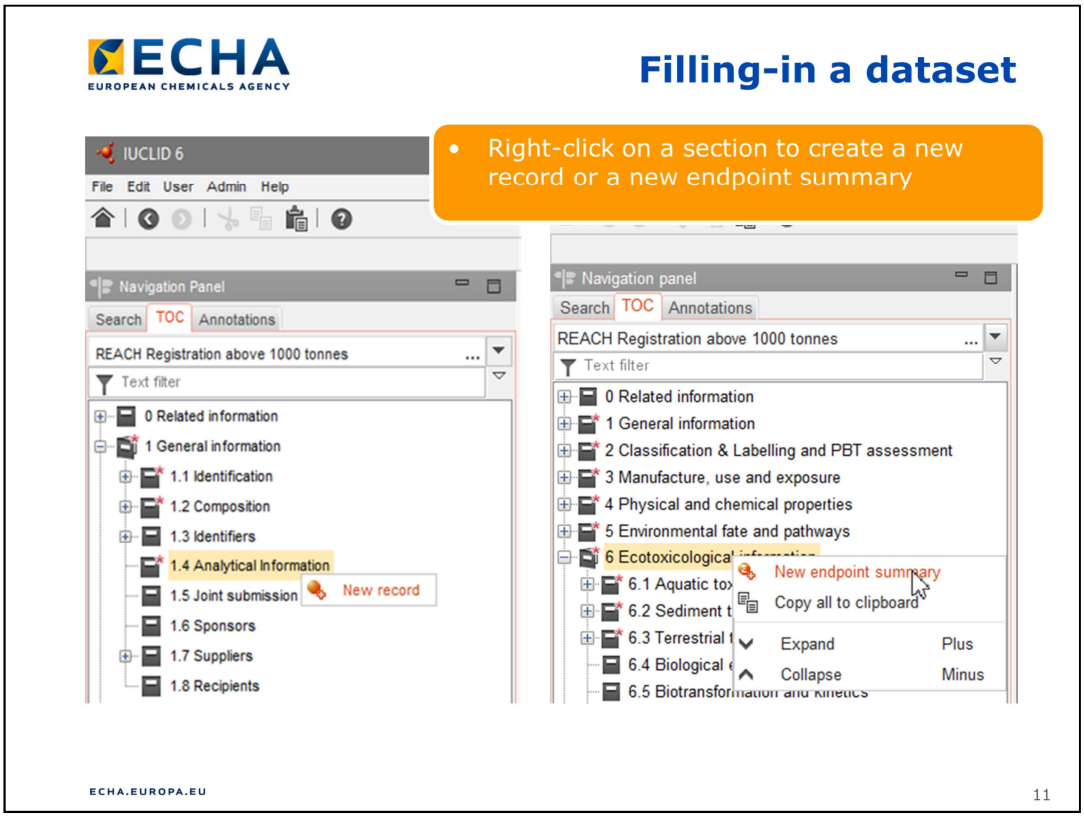
Section tree

- Mandatory sections are marked with a red asterisk *



Data requirements

- Lead dossier requirements compared to member dossier requirements.
- Lead is expected to provide the data in the endpoint sections on behalf of the members. The quality of that data is a joint obligation of all the joint submission (not only lead). If a member does not agree on the jointly submitted data, or if the joint submission tonnage band does not cover the member's tonnage, then the member can provide data in sections 4-8 on his own. It is considered opt-out and IUCLID section 14 needs to be filled with the opt-out data. Higher fee applies to registrations with opt-out.

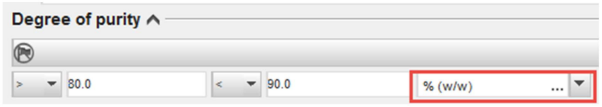


Filling-in a dataset

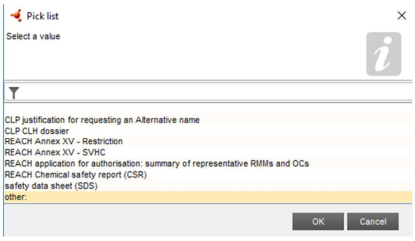
- IUCLID 6 is record based
- Right-click on a section name to create a new record or an endpoint summary

Tips for filling in a dataset 1/2

- Every value must be followed by a unit



- Every 'other' must be followed by a justification in the designated free text field



- Every justification must be (scientifically) meaningful

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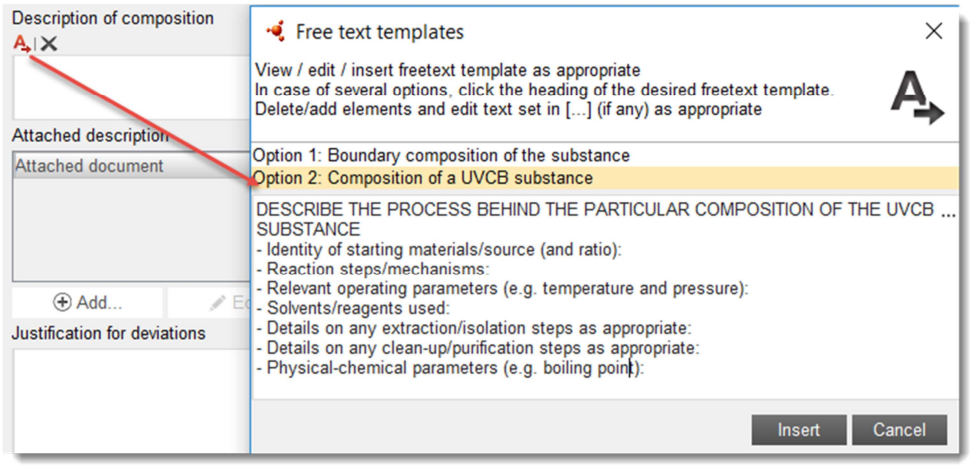
Tips for filling in a dataset 1/2

- Every value must be followed by a unit
- Every 'other' must be followed by a justification in the designated free text field
- Every justification must be (scientifically) meaningful

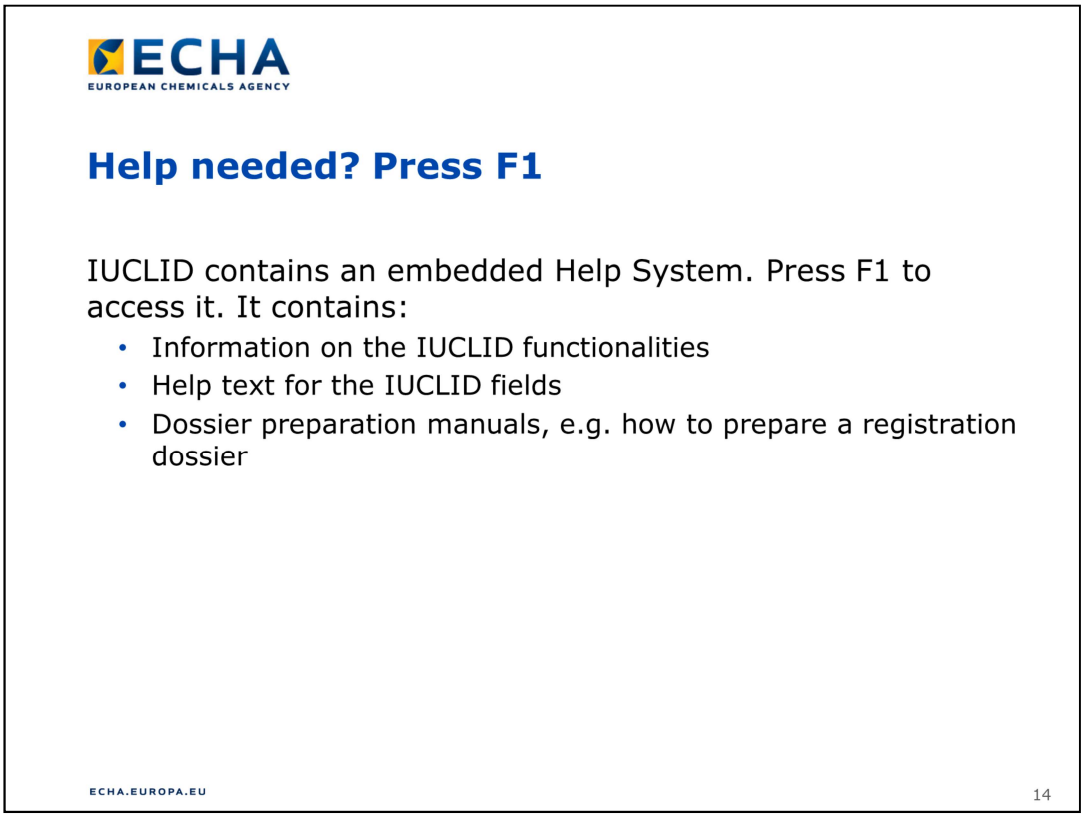
Tips for filling in a dataset 2/2

- Use free text templates as a guideline



Tips for filling in a dataset 2/2

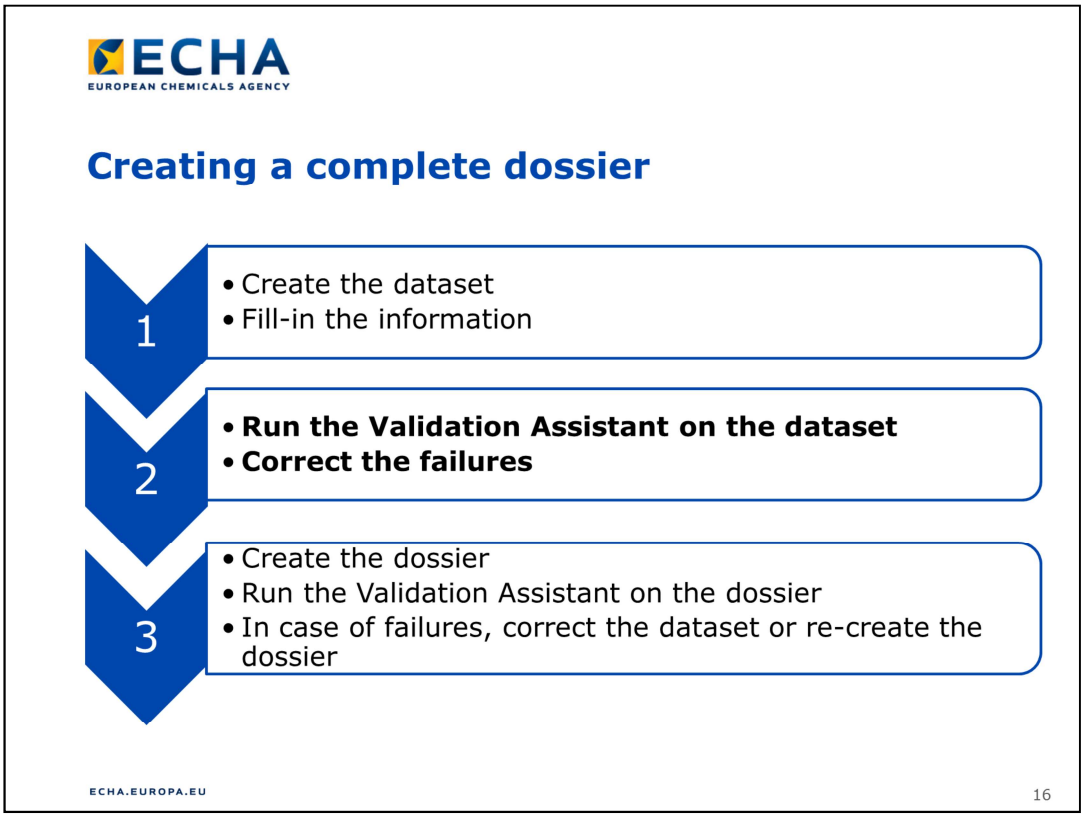
- Use free text templates as a guideline



Help needed? Press F1

- IUCLID contains an embedded Help System. Press F1 to access it. It contains:
  - Information on the IUCLID functionalities
  - Help text for the IUCLID fields
  - Dossier preparation manuals, e.g. how to prepare a registration dossier

Validation assistant



Creating a complete dossier

1.

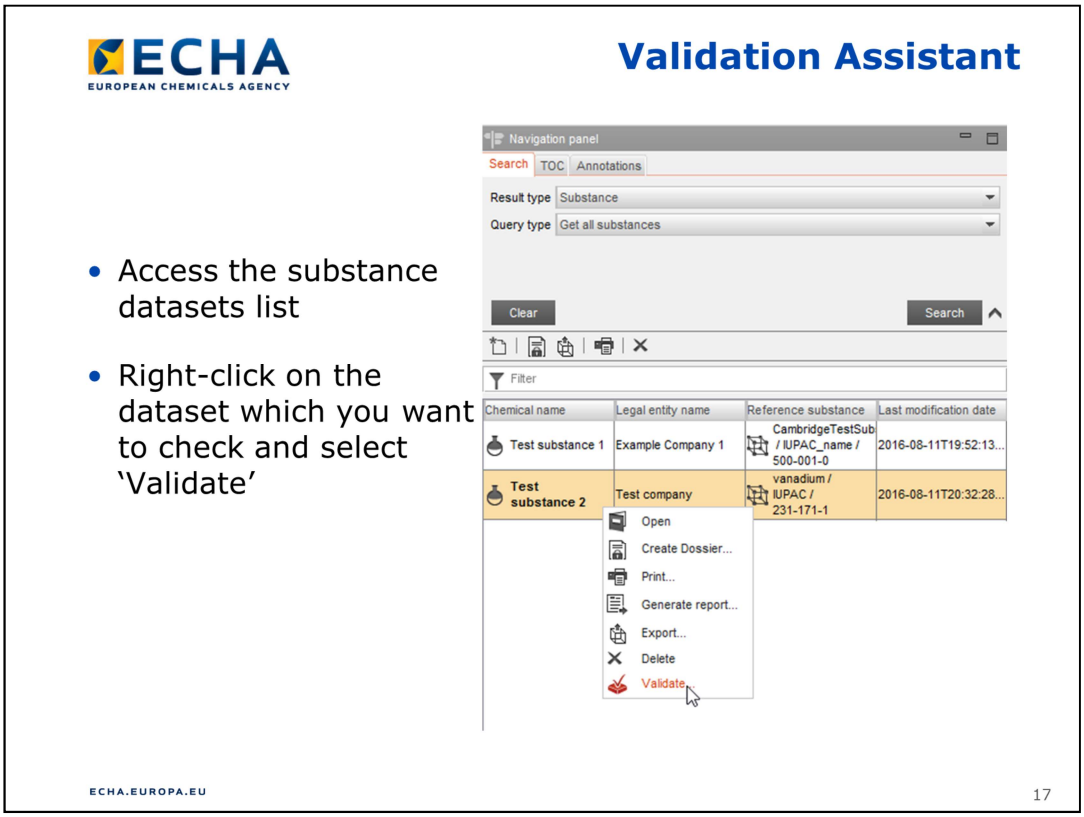
- Create the dataset
- Fill-in the information

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

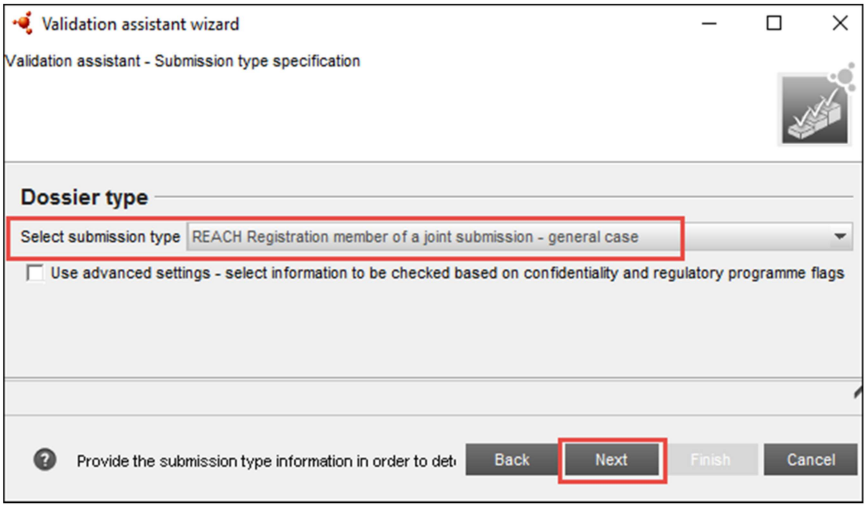


Validation Assistant

- Use the Validation Assistant (VA) to make sure that the substance dataset contains all the information required for your tonnage band and your submission type. Using the VA will minimize the risk of business rule failures and TCC failures but it will not exclude the possibility of failing BRC or TCC. Therefore, it is important to keep an eye on the tasks and messages in REACH-IT to receive any communication from ECHA in a timely manner and to react accordingly.
- VA shows the business rules that can be checked on IUCLID level but not the ones that depend on REACH-IT, e.g. joint submission name, last submission number, etc.
- VA shows all the automatically checked TCC rules. ECHA will perform additional manual checks that cannot be replicated by the VA.

Validation Assistant

- Select the submission type

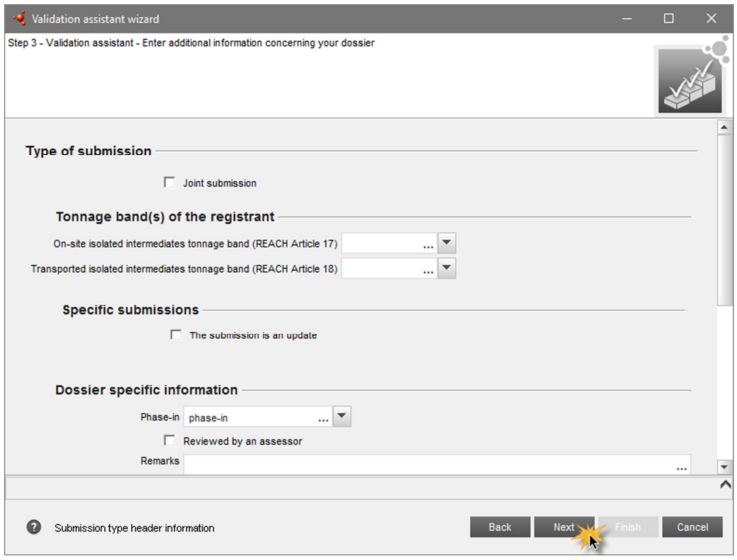


Validation Assistant

- Select the submission type
- Click next

Validation Assistant

- Provide the dossier header information to get the correct outcome



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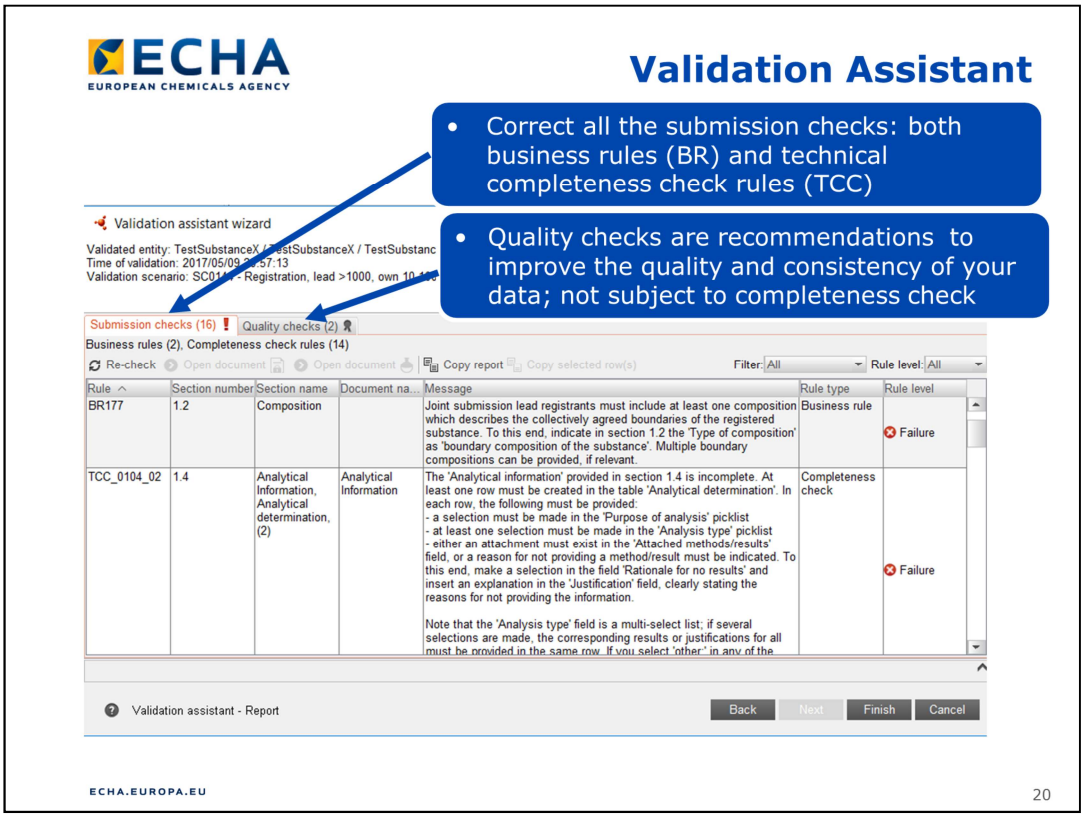
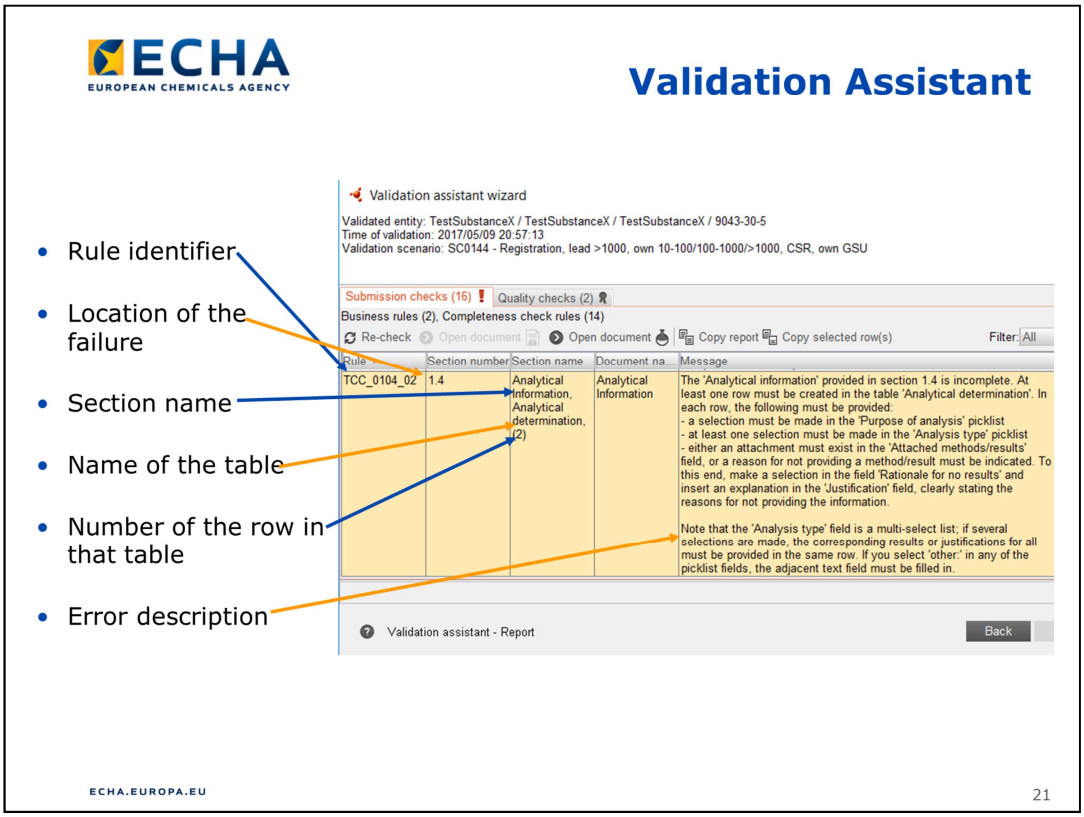
Validation Assistant

- Provide the dossier header information to get the correct outcome
- Click next



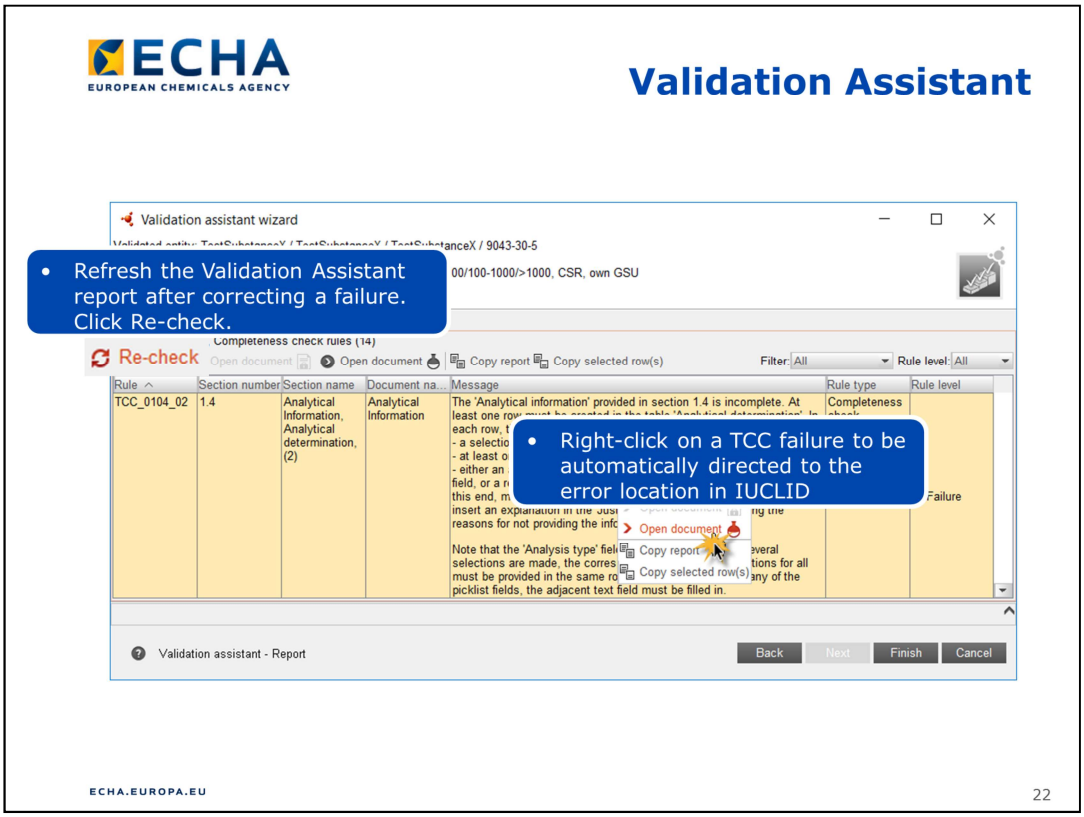
Validation Assistant

- In this example there is one business rule failure and one TCC failure which both need to be corrected before creating the dossier.



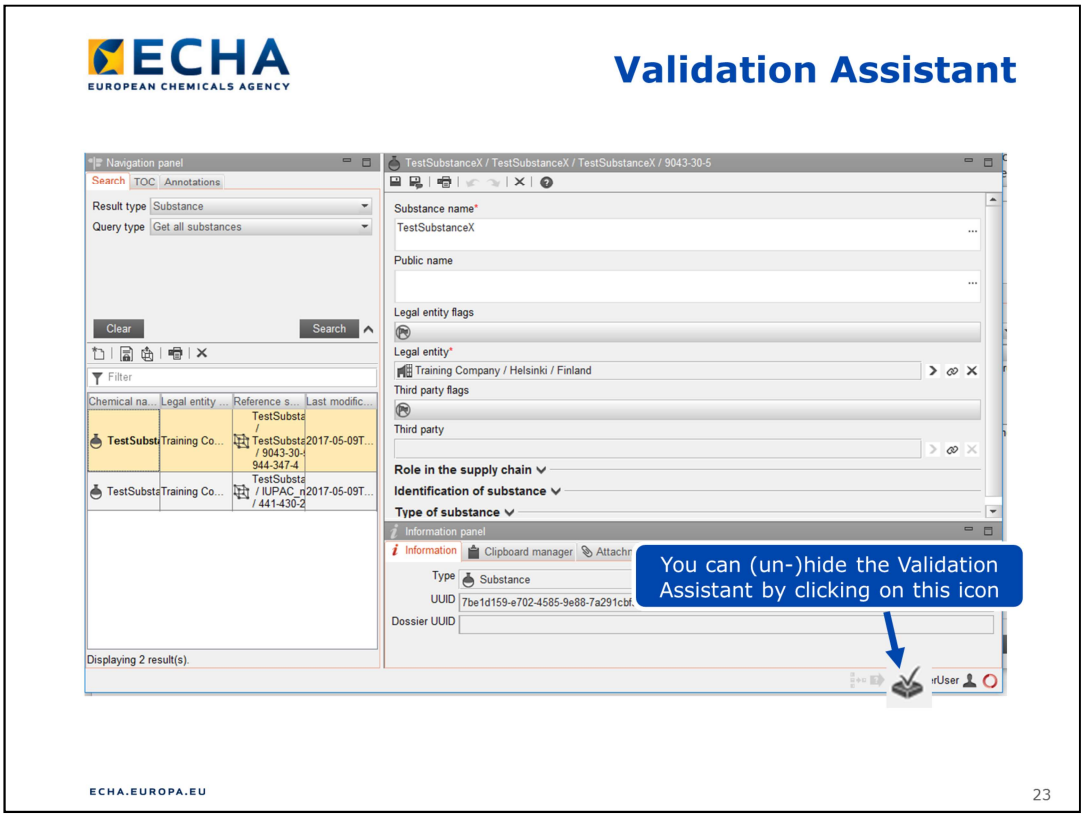
Validation Assistant

- This example gives you some hints on how to read the VA outcome.



Validation Assistant

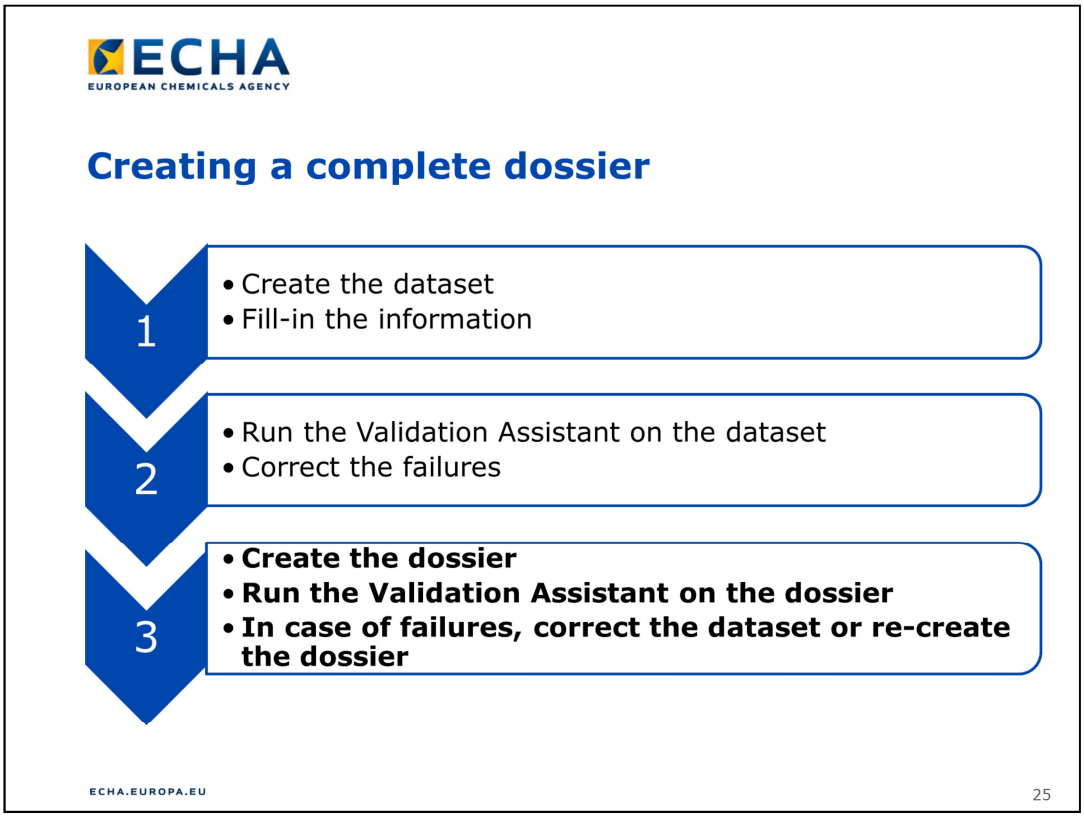
- Right-click on the failure message and select 'Open document'. IUCLID opens the location of the error. This does not work with the business rule failures, only with TCC errors. Alternatively you may navigate manually through the IUCLID section tree to the location of the error.
- Don't be surprised if you realise that clicking on the failure message does not take you anywhere. It means that this specific record is missing completely and you have to create one and fill it in.
- Read the failure message very carefully. It does tell you exactly what you have to do in order to correct the error.



Validation Assistant

- Occasionally it may happen that you 'lose' your VA. When trying to open it again you receive an error message saying that it is already open. You can 'find' the VA by clicking on the VA icon in the bottom right corner of your IUCLID page.

Dossier creation



Creating a complete dossier

1.

- Create the dataset
- Fill-in the information

2.

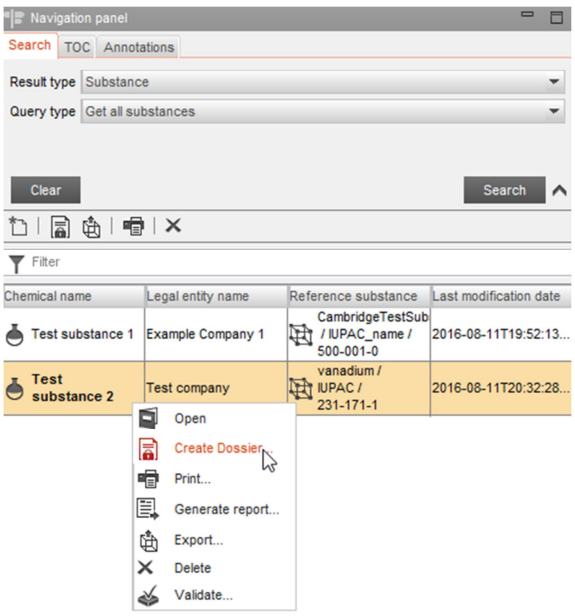
- Run the Validation Assistant on the dataset
- Correct the failures

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

- Select the dataset
- Right-click and create dossier

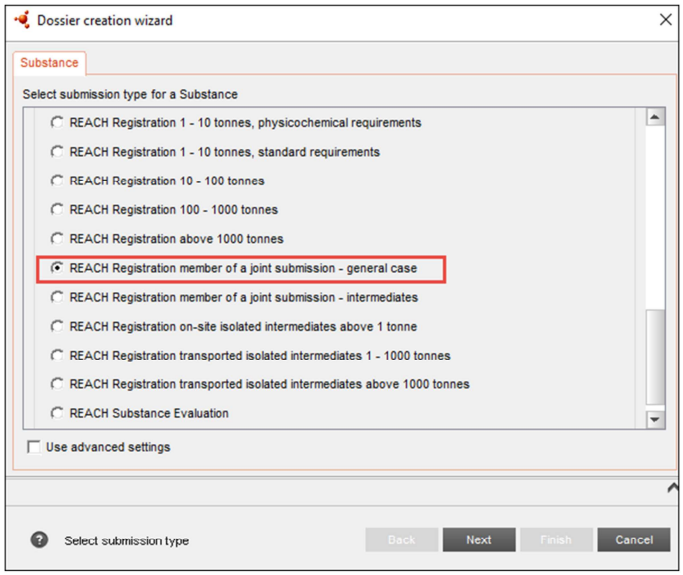


Dossier creation

- Once all the failures have been corrected on the dataset level you may create the dossier.

Dossier creation wizard

- Select the correct dossier type



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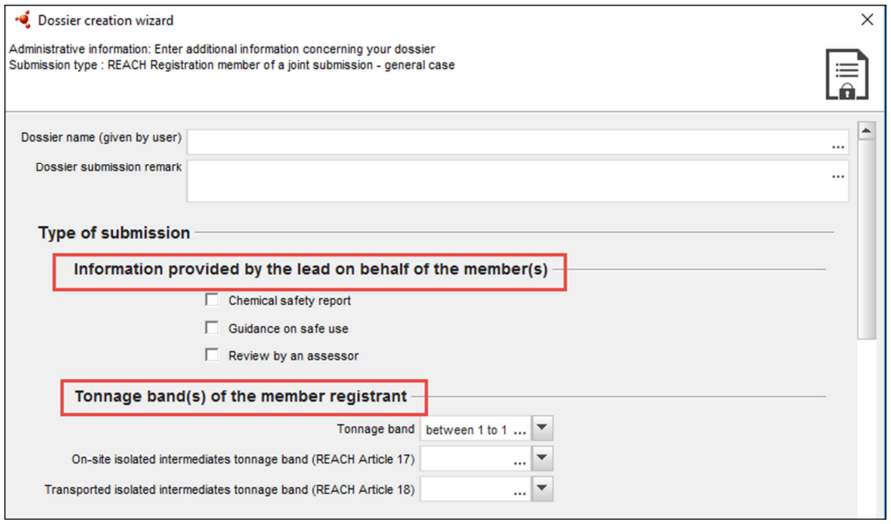
Dossier creation wizard

- Select the correct dossier template. There are only two templates relevant for the member registrants. See also slide 12.
- If you are lead registrant then the tonnage band of the dossier template must cover the agreed joint registration tonnage. You will be able to select your own individual tonnage in the next step.

Dossier creation wizard

- Fill-in the dossier header



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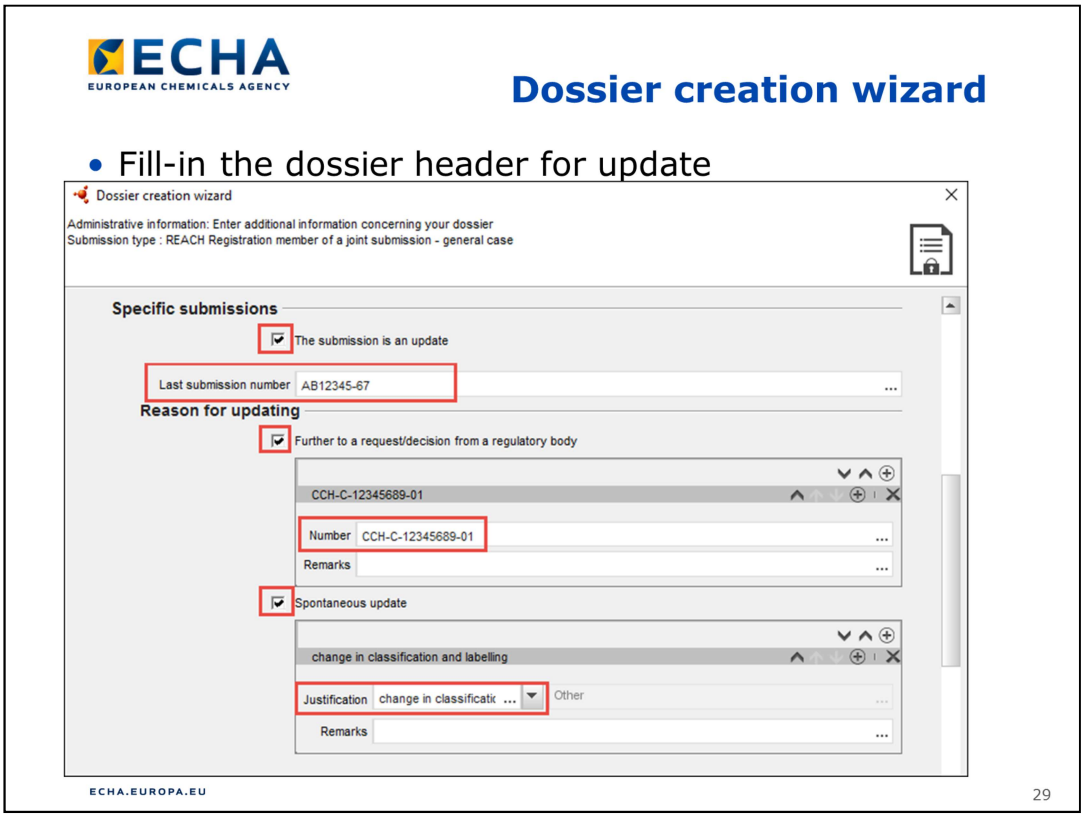
Dossier creation wizard

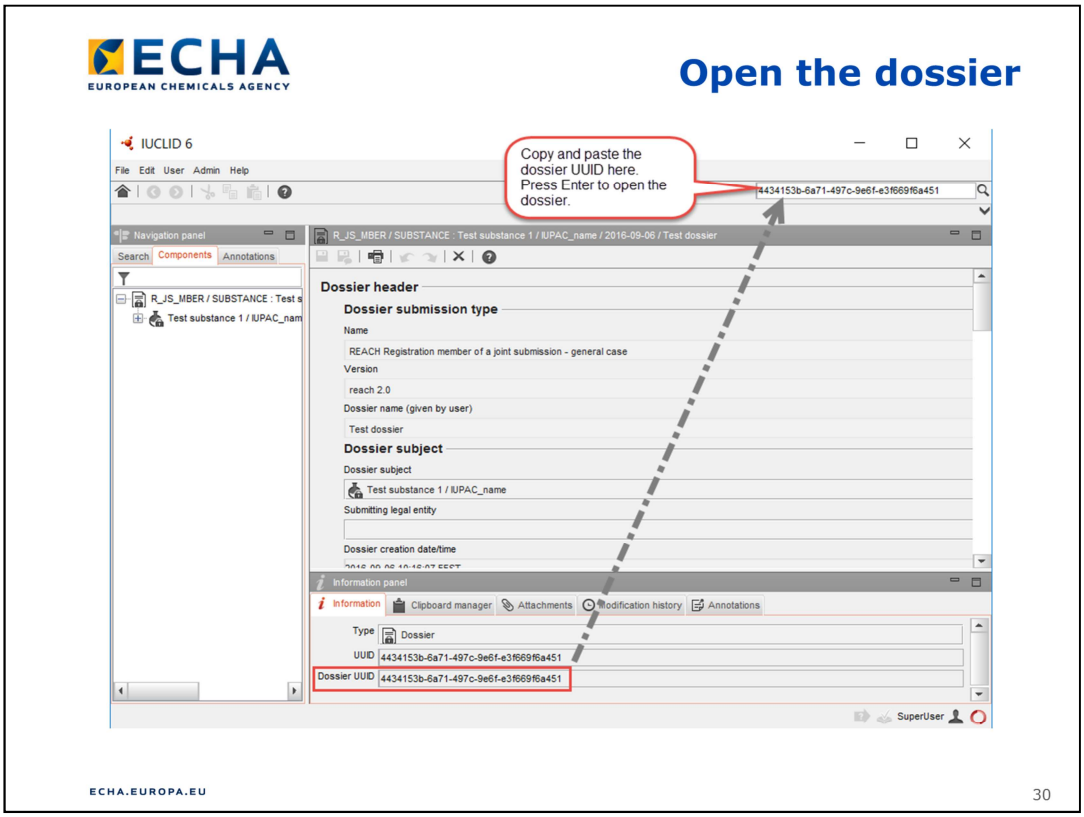
- If the CSR and/or GSU are provided by the lead on behalf of the members then these tick-boxes must be ticked on the dossier header.

- You will need to indicate your individual tonnage., e.g., joint registration covers the tonnage range 100-1000 t/y but lead's individual tonnage is only 1-10 t/y. The example screenshot is from the member dossier creation wizard but the same logic applies also to the lead registrant's dossier creation wizard.



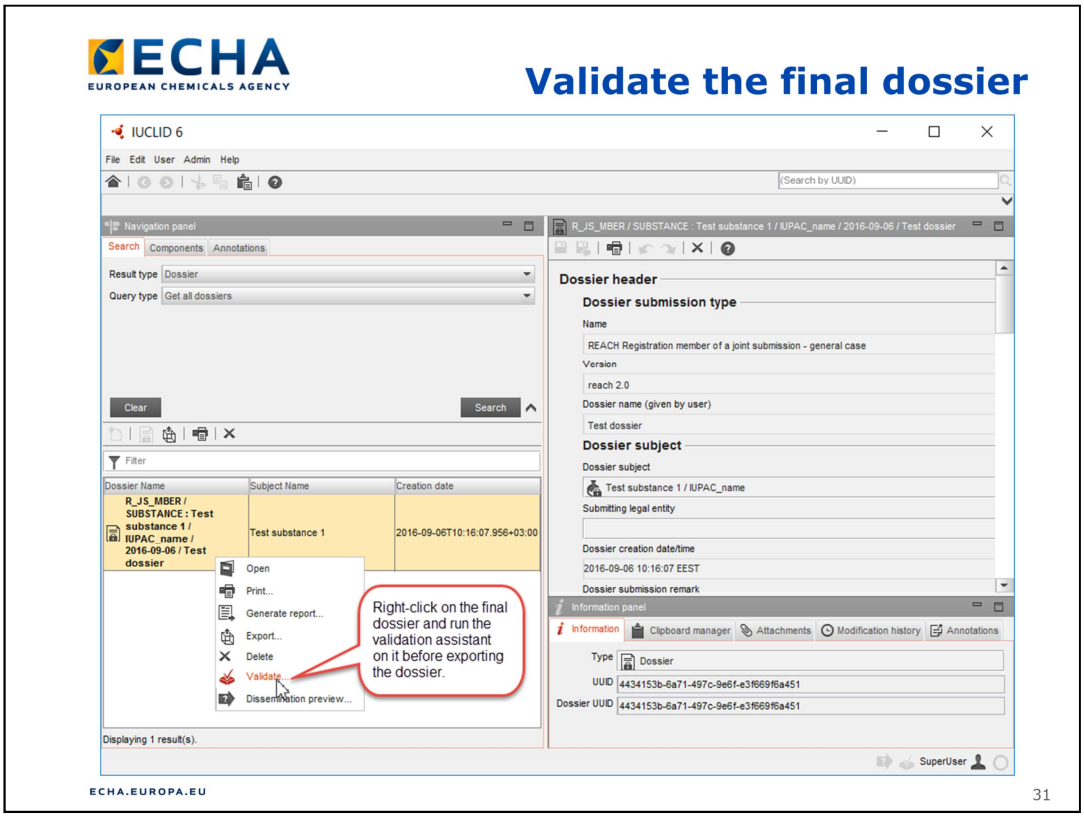
Dossier creation wizard

- Once you have successfully registered your substance you may have a need to update your dossier – submit a **spontaneous update**. Also, if your dossier happens to fail TCC or you will be requested by ECHA to provide further information for other reasons, you will need to submit an update dossier – **requested update**. The above screenshot shows the mandatory fields for an update dossier. Note that if your dossier fails TCC then it is advisable to correct only the missing or faulty information. Any additional and new information you can submit as a spontaneous update after the TCC requested update is considered correct by ECHA.



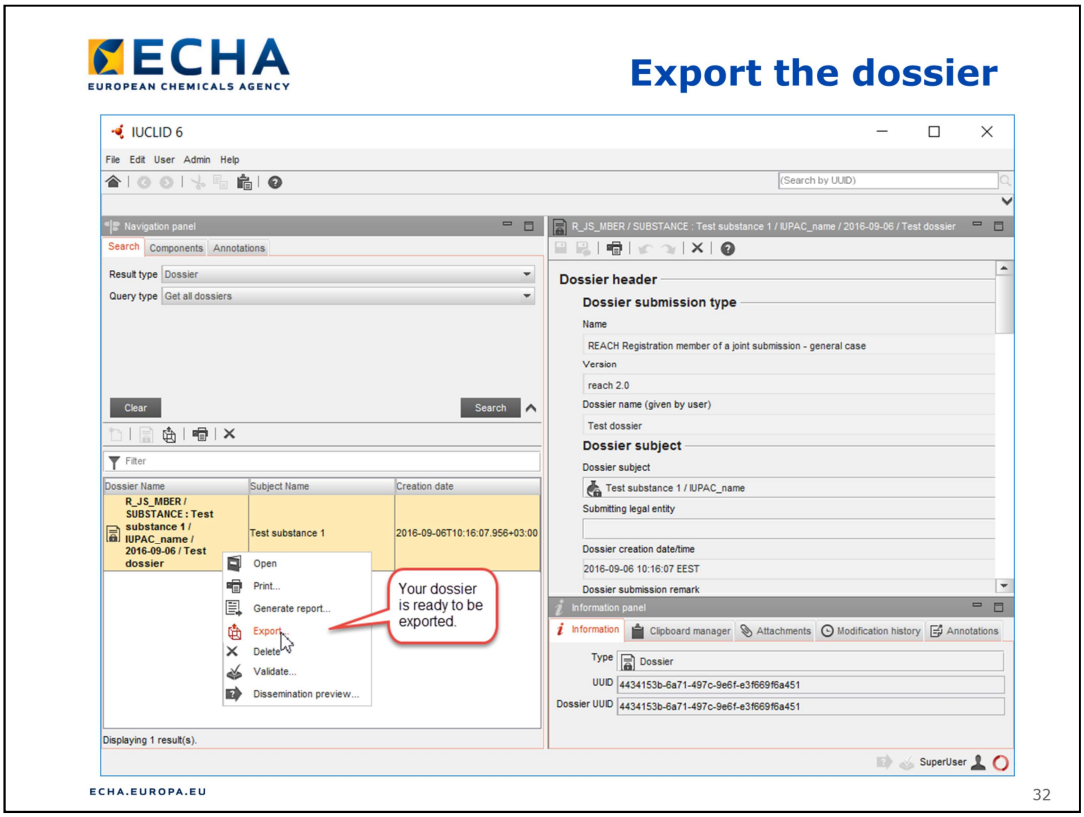
Open the dossier

- Copy the dossier UUID from the Dossier UUID field in the bottom of the screen
- Paste the dossier UUID in the free-text field located at top right of the screen
- Press Enter to open the dossier



Validate the final dossier

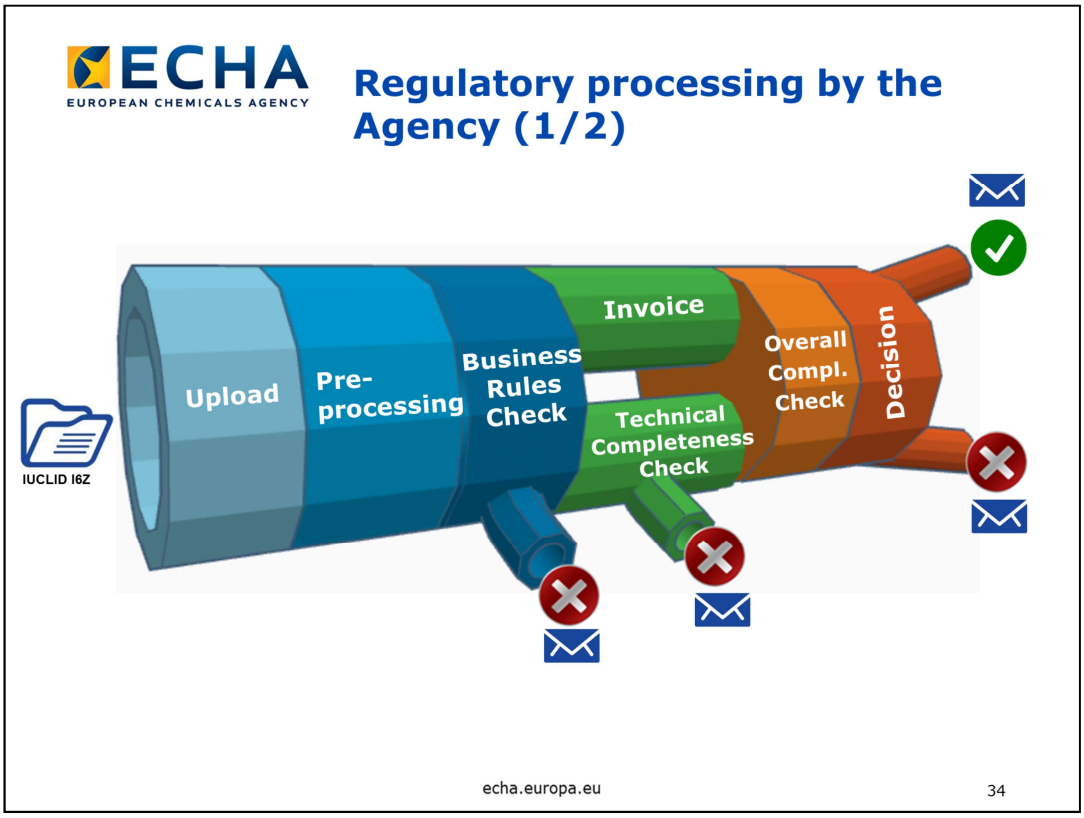
- New errors may have occured during the dossier creation. Therefore it is important to validate also the final dossier before exporting it, e.g. wrong dossier template was selected. If any errors are detected you will need to go back to your substance dataset, correct the failures and create a new dossier.



Export the dossier

- Your dossier is ready to be exported from IUCLID and to be submitted to REACH-IT.

Regulatory processing



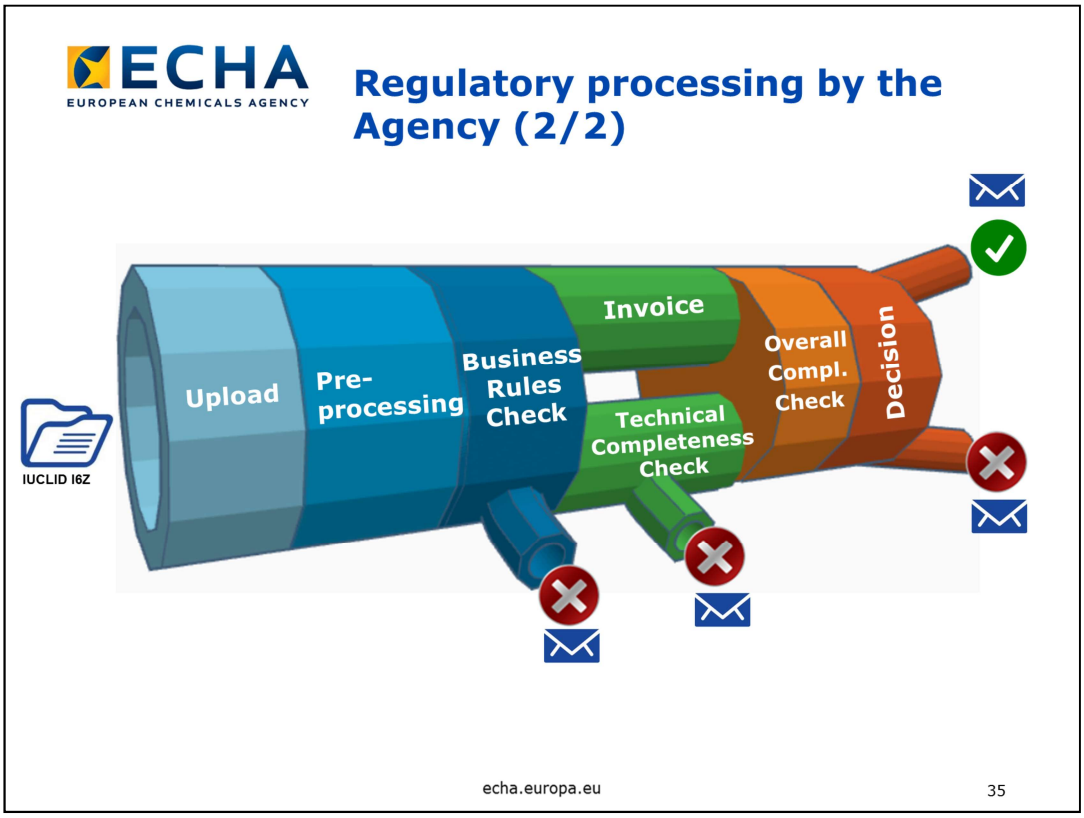
Regulatory processing by the Agency

What happens to your registration dossier after submitting it to ECHA?

Upload: The dossier enters into 'pipeline'

Pre-processing: The file undergoes several IT checks, such as virus check, file format validation (verified that it is an i6z file), etc.

Business Rules Check is a set of admin checks, e.g. submitted the correct type of dossier (initial or update, member or lead, company address). If BRC is failed the company gets a task with the failure message and instructions to resubmit. No limit on the number of attempts. The dossier is considered 'submitted to ECHA' once the business rules check is passed. That would be the submission date of the registration dossier.



Two parallel processes:

1. Invoice is being issued

2. Technical Completeness Check (TCC) includes both automatic and manual checks to verify that the data required by REACH is provided inside the dossier. If TCC fails, there is only one more attempt within a given deadline, else submission gets rejected and any money related to this submission will not be refunded. TCC may take from some minutes (if everything is straight forward and OK) up to 21 days as per REACH art. 20 (if the workload in the pipeline is high or if the dossier is complex). Note that if the dossier is submitted within 2 months before the 2018 registration deadline then TCC may take up to 3 months after the deadline (REACH art. 20).

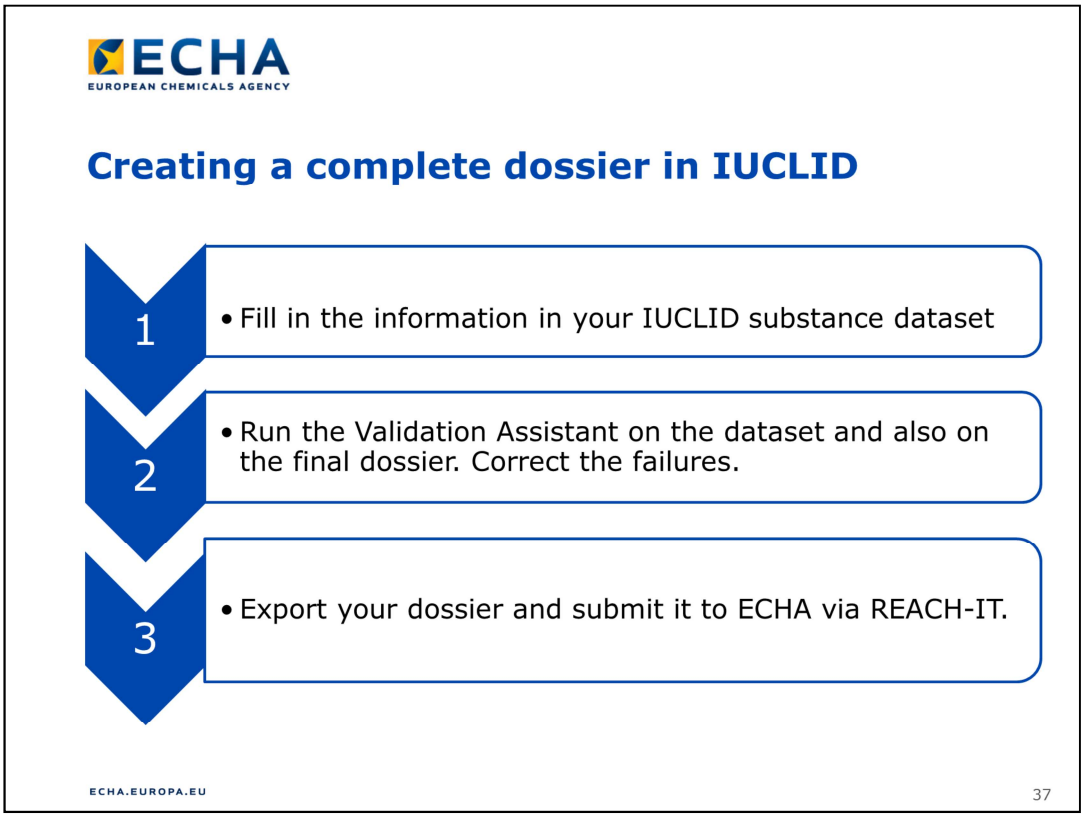
Overall Completeness Check (OCC) – Members of the joint submission can submit their dossiers as soon as the lead dossier has passed the business rules. They will be 'parked' at the OCC step until the lead dossier is completed.

Decision sending – with a positive decision a registration number is issued; negative decision means rejection of the submission and the whole process needs to be restarted. If an intial submission gets rejected then it means that **no** registration number will be granted. If an Update dossier gets rejected then it means that only the latest update submission gets rejected; it does not affect the registration number.

Further steps: Ouside the pipeline and after the registration is confirmed: data gets published on the ECHA website (unless claimed confidential); dossier may be selected for further assessments, e.g. Compliance check.

All these steps are communicated to the registrant via REACH-IT.

Summary



Creating a complete dossier in IUCLID

1.

- Fill in the information in your IUCLID substance dataset

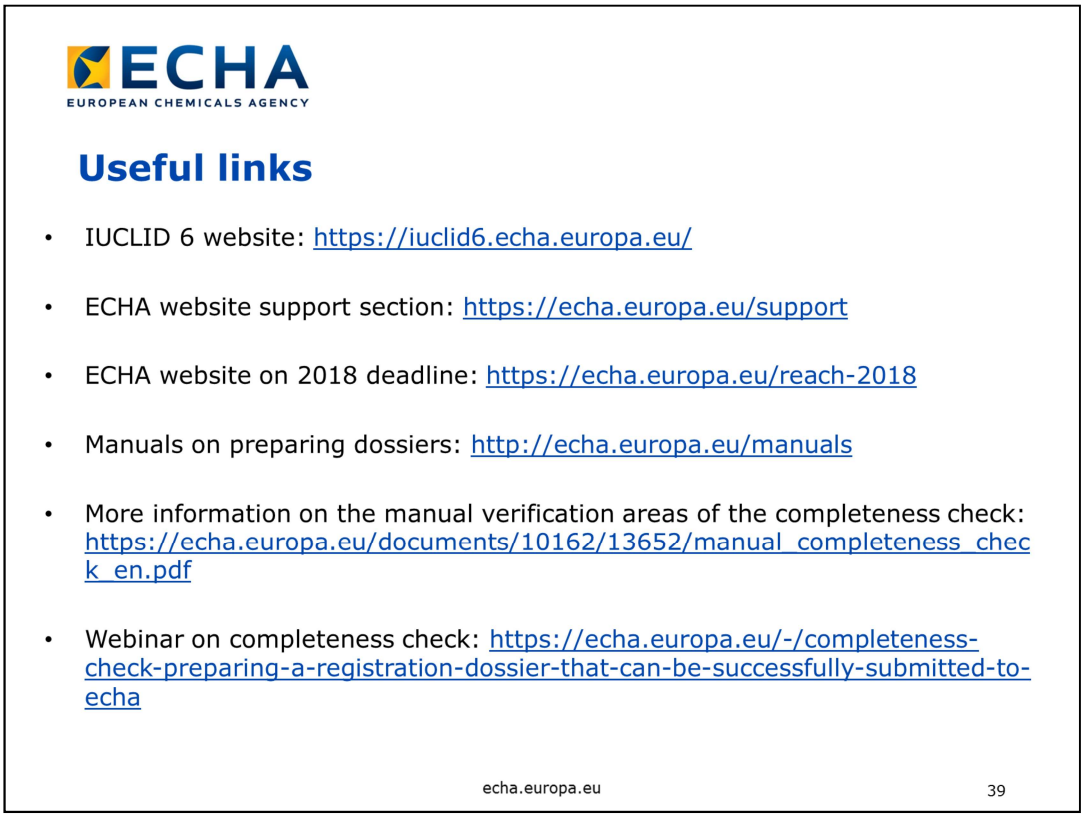
2.

- Run the Validation Assistant on the dataset and also on the final dossier. Correct the failures.

3.

- Export your dossier and submit it to ECHA via REACH-IT

Support and guidance



Useful links

- IUCLID 6 website: https://iuclid6.echa.europa.eu/
- ECHA website support section: https://echa.europa.eu/support
- ECHA website on 2018 deadline: https://echa.europa.eu/reach-2018
- Manuals on preparing dossiers: http://echa.europa.eu/manuals
- Webinar on completeness check: https://echa.europa.eu/-/completeness-check-preparing-a-registration-dossier-that-can-be-successfully-submitted-to-echa

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