

REACH IT tools training:

- IUCLID 6
- Completeness Check
- Regulatory processing

November 2017

Directorate of Registration
European Chemicals Agency

REACH IT tools training:

- IUCLID 6
- Completeness Check
- Regulatory processing

Agenda

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



Agenda

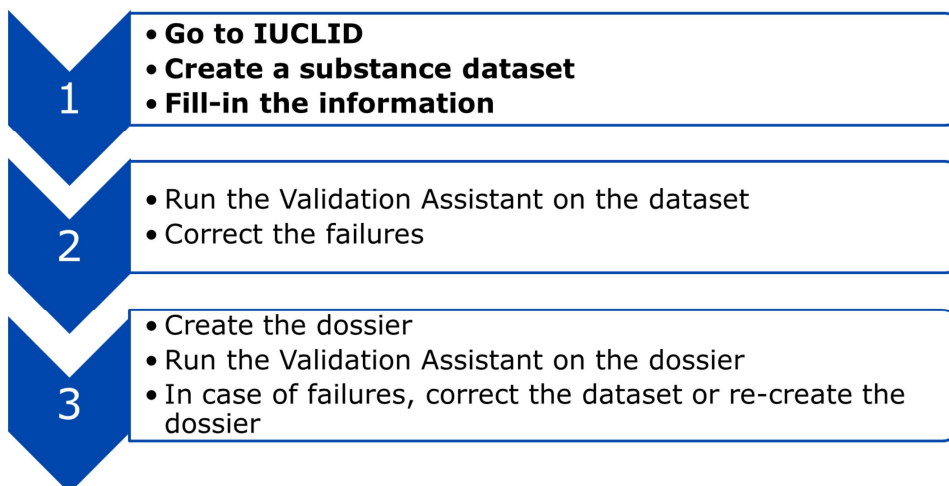
- IUCLID 6 functionalities
- Validation assistant
- Dossier creation
- Regulatory processing
- Summary
- Support and guidance

IUCLID 6 functionalities



IUCLID 6 functionalities

Creating a complete dossier in IUCLID



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

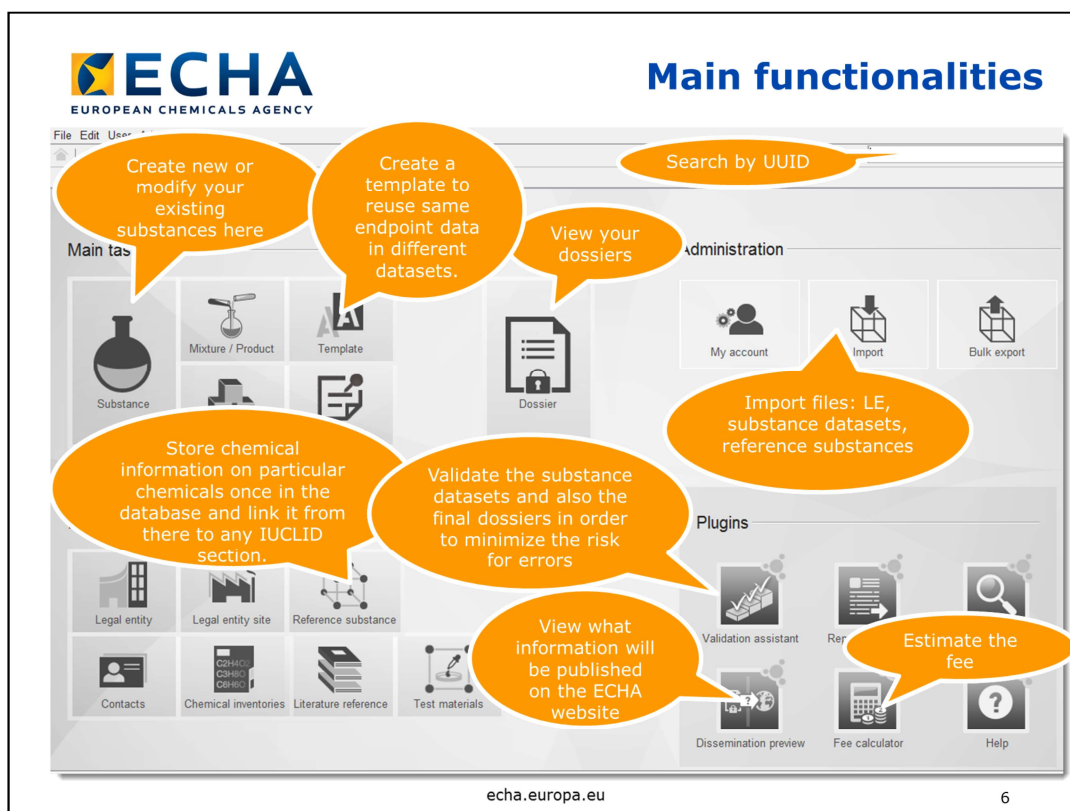
The screenshot shows the IUCLID 6 website. At the top left is the ECHA logo. To its right is the URL. Below the logo is the IUCLID 6 logo. A search bar is on the right with a 'Sign In' link. A navigation bar contains links: Home, IUCLID Product, Download Software, Support, and News. Below this is a 'IUCLID > Home' breadcrumb. On the left, a callout bubble points to a 'Download' button on a software interface preview, with the text 'Sign in and download the application'. On the right, another callout bubble points to a news section, with the text 'Download data, e.g. reference substances; FAQ regarding installation, migration from IUCLID5 to IUCLID6, etc. Technical manuals'. The news section includes dates like '28 April 2017' and '24 March 2017'.

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

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

Chemical name	Legal entity name	Reference substance	Last modification date
TestSubstanceX	Training Company	TestSubstanceX / TestSubstanceX / 9043-30-5 / 944-347-4	2017-05-09T20:29:49.189...
TestSubstanceZ	Training Company	TestSubstance2 / IUPAC_name / 441-430-2	2017-05-09T20:29:38.252...

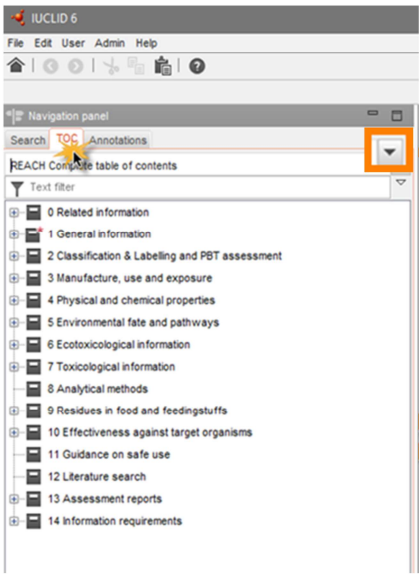
Datasets' list

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

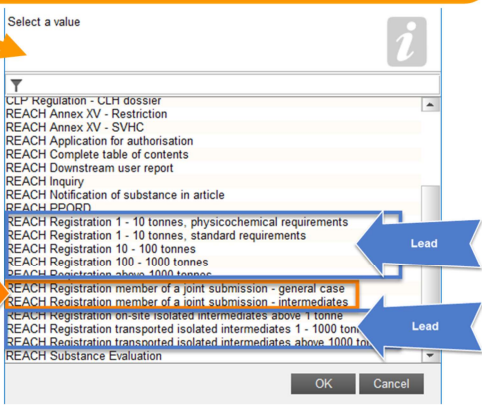


ECHA
EUROPEAN CHEMICALS AGENCY

Dataset's content



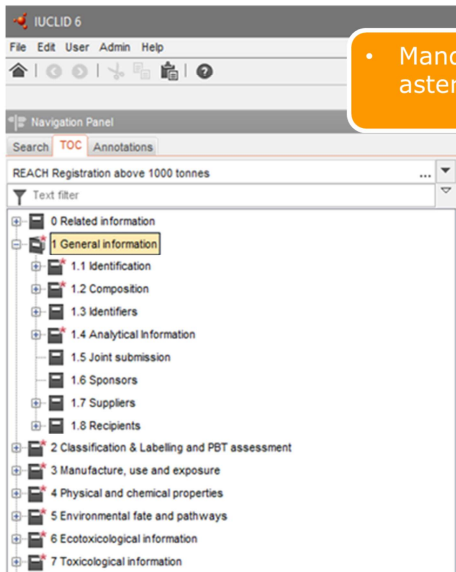
- Click on 'TOC' to display the table of contents of the dataset
- By default, the view is 'REACH Complete'
- Select the relevant view from the black arrow



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8

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 *

- Lead data requirements compared to the member data requirements

Navigation panel	
Search TOC Annotations	Search TOC Annotations
REACH Registration 1 - 10 tonnes, standard require ...	REACH Registration member of a joint submission - ...
Text filter	Text filter
<ul style="list-style-type: none"> 0 Related information 1 General information 2 Classification & Labelling and PBT assessment 3 Manufacture, use and exposure 4 Physical and chemical properties 5 Environmental fate and pathways 6 Ecotoxicological information 7 Toxicological information 8 Analytical methods 11 Guidance on safe use 12 Literature search 13 Assessment reports 14 Information requirements 	<ul style="list-style-type: none"> 0 Related information 1 General information 2 Classification & Labelling and PBT assessment 3 Manufacture, use and exposure 4 Physical and chemical properties 5 Environmental fate and pathways 6 Ecotoxicological information 7 Toxicological information 8 Analytical methods 11 Guidance on safe use 12 Literature search 13 Assessment reports 14 Information requirements

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.

- Right-click on a section to create a new record or a new endpoint summary

The image displays two screenshots of the IUCLID 6 software interface. The left screenshot shows the 'Navigation Panel' with a tree view of sections. Section 1.4 'Analytical Information' is highlighted, and a 'New record' button is visible. The right screenshot shows the same interface with a right-click context menu open over section 6 'Ecotoxicological information'. The menu options include 'New endpoint summary' and 'Copy all to clipboard'.

Filling-in a dataset

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

- Every value must be followed by a unit

Degree of purity ^

> 80.0 < 90.0 % (w/w) ...

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

Pick list
Select a value

CLP justification for requesting an Alternative name
CLP CLH dossier
REACH Annex XV - Restriction
REACH Annex XV - SVHC
REACH application for authorisation: summary of representative RHMIs and OCs
REACH Chemical safety report (CSR)
safety data sheet (SDS)
other:

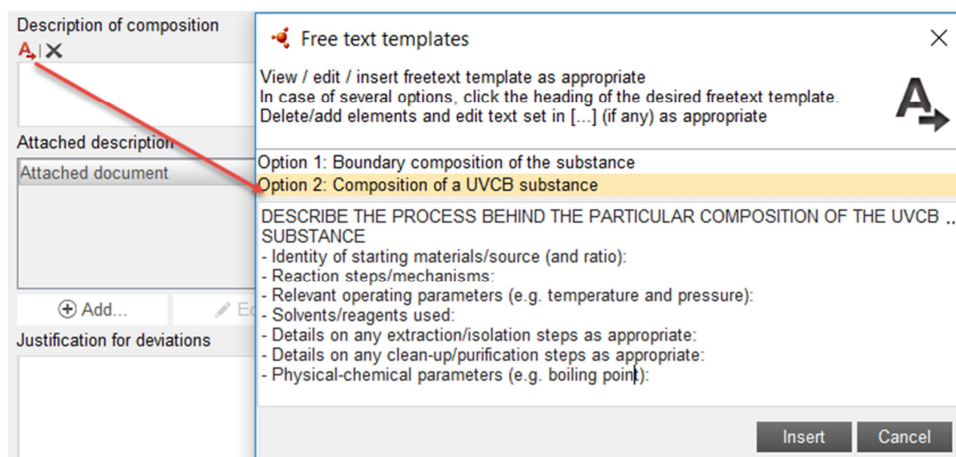
OK Cancel

- Every justification must be (scientifically) meaningful

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

- 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

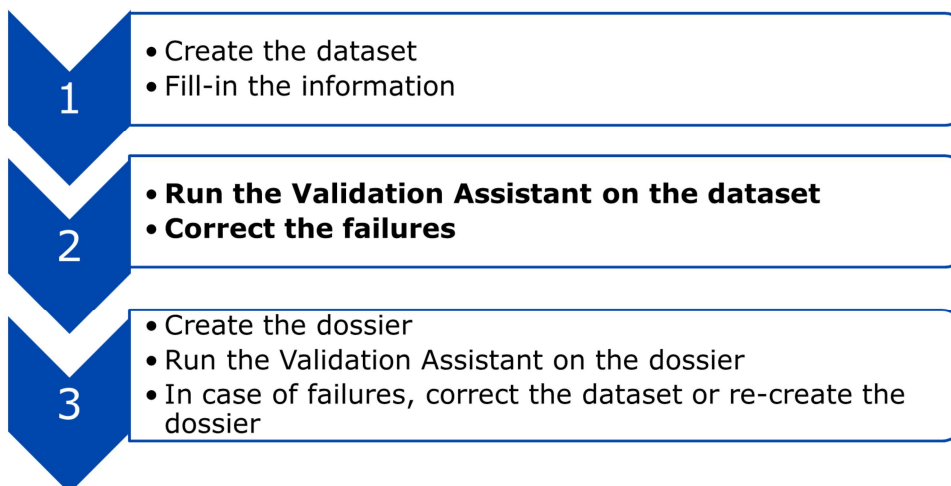
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Validation assistant



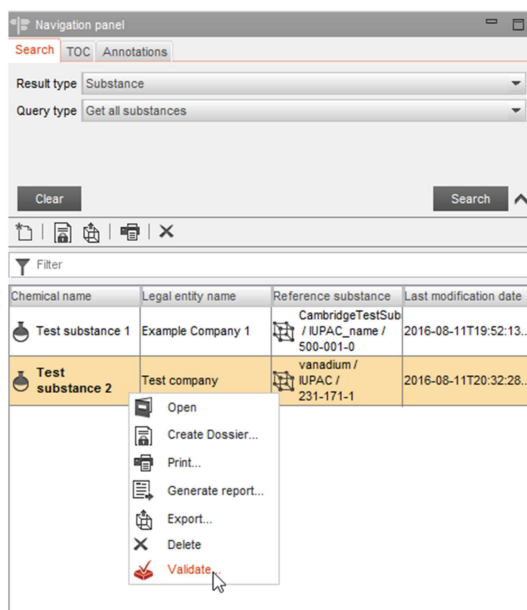
Creating a complete dossier



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

- Access the substance datasets list
- Right-click on the dataset which you want to check and select 'Validate'



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.

- Select the submission type

Validation assistant wizard

Validation assistant - Submission type specification

Dossier type

Select submission type REACH Registration member of a joint submission - general case

☐ Use advanced settings - select information to be checked based on confidentiality and regulatory programme flags

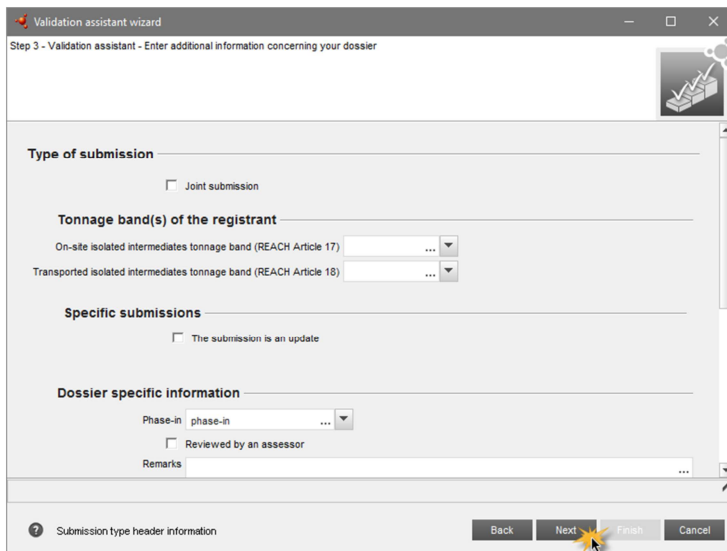
Provide the submission type information in order to det

Back Next Finish Cancel

Validation Assistant

- Select the submission type
- Click next

- Provide the dossier header information to get the correct outcome



Validation assistant wizard

Step 3 - Validation assistant - Enter additional information concerning your dossier

Type of submission

☐ Joint submission

Tonnage band(s) of the registrant

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 ...

☐ Reviewed by an assessor

Remarks ...

Submission type header information

Back Next Finish Cancel

Validation Assistant

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

- Correct all the submission checks: both business rules (BR) and technical completeness check rules (TCC)

- Quality checks are recommendations to improve the quality and consistency of your data; not subject to completeness check

Validation assistant wizard

Validated entity: TestSubstanceX / TestSubstanceX / TestSubstanceX
Time of validation: 2017/05/09 10:57:13
Validation scenario: SC01 - Registration, lead >1000, own 10-14

Submission checks (16) | Quality checks (2)

Business rules (2), Completeness check rules (14)

Re-check | Open document | Open document | Copy report | Copy selected row(s)

Filter: All | Rule level: All

Rule	Section number	Section name	Document no.	Message	Rule type	Rule level
BR177	1.2	Composition		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_0104_02	1.4	Analytical Information, Analytical determination, (2)	Analytical Information	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 'Justification' field, clearly stating the reasons for not providing the information. Note that the 'Analysis type' field is a multi-select list; if several selections are made, the corresponding results or justifications for all must be provided in the same row. If you select 'other' in any of the	Completeness check	Failure

Validation assistant - Report

Back Next Finish Cancel

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.

- Rule identifier
- Location of the failure
- Section name
- Name of the table
- Number of the row in that table
- Error description

Validation assistant wizard

Validated entity: TestSubstanceX / TestSubstanceX / TestSubstanceX / 9043-30-5
 Time of validation: 2017/05/09 20:57:13
 Validation scenario: SC0144 - Registration, lead >1000, own 10-100/100-1000/>1000, CSR, own GSU

Submission checks (16) ! Quality checks (2) ?

Business rules (2), Completeness check rules (14)

Re-check Open document Open document Copy report Copy selected row(s) Filter: All

Rule	Section number	Section name	Document na...	Message
TCC_0104_02	1.4	Analytical Information, Analytical determination, (2)	Analytical Information	<p>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:</p> <ul style="list-style-type: none"> - 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 'Justification' field, clearly stating the reasons for not providing the information. <p>Note that the 'Analysis type' field is a multi-select list; if several selections are made, the corresponding results or justifications for all must be provided in the same row. If you select 'other' in any of the picklist fields, the adjacent text field must be filled in.</p>

Validation assistant - Report Back

Validation Assistant

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

[illegible]

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

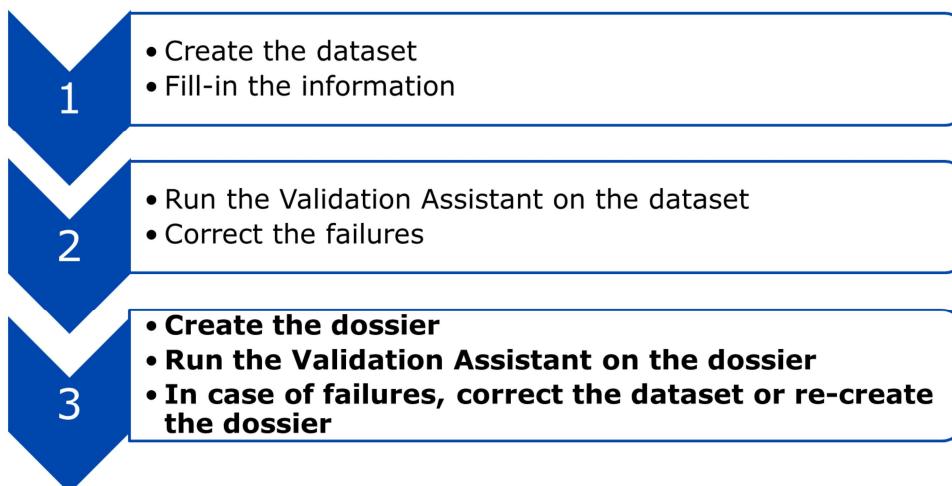
- Occasionally it may happen that you 'lose' your VA. When trying to open it again you receive an error message saying that it is already open. You can 'find' the VA by clicking on the VA icon in the bottom right corner of your IUCLID page.

Dossier creation



Dossier creation

Creating a complete 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

- Select the dataset
- Right-click and create dossier

The screenshot shows the ECHA Dossier creation interface. At the top, there is a 'Navigation panel' with tabs for 'Search', 'TOC', and 'Annotations'. Below this, there are dropdown menus for 'Result type' (set to 'Substance') and 'Query type' (set to 'Get all substances'). A 'Clear' button and a 'Search' button are also present. Below the search panel is a table with the following columns: 'Chemical name', 'Legal entity name', 'Reference substance', and 'Last modification date'. The table contains two rows: 'Test substance 1' and 'Test substance 2'. A right-click context menu is open over the 'Test substance 2' row, showing options: 'Open', 'Create Dossier' (highlighted with a red box and a mouse cursor), 'Print...', 'Generate report...', 'Export...', 'Delete', and 'Validate...'.

Chemical name	Legal entity name	Reference substance	Last modification date
Test substance 1	Example Company 1	CambridgeTestSub / IUPAC_name / 500-001-0	2016-08-11T19:52:13...
Test substance 2	Test company	vanadium / IUPAC / 231-171-1	2016-08-11T20:32:28...

Dossier creation

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

- Select the correct dossier type

Dossier creation wizard

Substance

Select submission type for a Substance

- ☐ 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

☐ Use advanced settings

? Select submission type

Back Next Finish Cancel

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.

- Fill-in the dossier header

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.

- Fill-in the dossier header for update

The screenshot shows the 'Dossier creation wizard' window. At the top, it says 'Administrative information: Enter additional information concerning your dossier' and 'Submission type : REACH Registration member of a joint submission - general case'. The main section is titled 'Specific submissions'. Under this, there are two radio buttons: 'The submission is an update' (selected) and 'The submission is a new submission'. Below the selected option, there is a text field for 'Last submission number' with the value 'AB12345-67'. The next section is 'Reason for updating', which has two radio buttons: 'Further to a request/decision from a regulatory body' (selected) and 'Spontaneous update'. Under the selected option, there is a table with one row. The table has columns for 'Number' and 'Remarks'. The 'Number' field contains 'CCH-C-12345689-01'. Below the table, there is a section for 'Spontaneous update' with a radio button. Under this, there is a table with one row. The table has columns for 'Justification' and 'Remarks'. The 'Justification' field contains 'change in classification and labelling' and the 'Remarks' field is empty. The ECHA logo and 'ECHA.EUROPA.EU' are at the bottom left, and the page number '29' is at the bottom right.

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

The screenshot shows the IUCLID 6 software interface. At the top, there is a menu bar (File, Edit, User, Admin, Help) and a search bar. Below the menu bar, the 'Navigation panel' on the left shows a tree structure with 'RJS_MBER / SUBSTANCE : Test substance 1 / IUPAC_name' selected. The main area displays the 'Dossier header' form, which includes fields for 'Dossier submission type' (Name, Version, Dossier name), 'Dossier subject' (Dossier subject, Submitting legal entity, Dossier creation date/time), and 'Information panel' (Type, UUID, Dossier UUID). A red box highlights the 'Dossier UUID' field, which contains the value '4434153b-6a71-497c-9e6f-e3f669f6a451'. A callout box with a red border and a red arrow points to the top right of the interface, containing the text: 'Copy and paste the dossier UUID here. Press Enter to open the dossier.' A dashed arrow points from the 'Dossier UUID' field to the top right text field.

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

The screenshot displays the IUCLID 6 application window. On the left, the 'Navigation panel' shows a search for 'Dossier' with 'Get all dossiers' as the query type. Below this is a table of results:

Dossier Name	Subject Name	Creation date
RJS_MBER / SUBSTANCE : Test substance 1 / IUPAC_name / 2016-09-06 / Test dossier	Test substance 1	2016-09-06T10:16:07.956+03:00

A right-click context menu is open over the first row, with the 'Validate' option highlighted. A red callout box points to this option with the text: 'Right-click on the final dossier and run the validation assistant on it before exporting the dossier.'

The right side of the interface shows the 'Dossier header' and 'Dossier subject' details for the selected dossier. The 'Dossier header' includes fields for Name, Version, Dossier name, and Test dossier. The 'Dossier subject' includes fields for Test substance, Submitting legal entity, and Dossier creation date/time.

Validate the final dossier

- New errors may have occurred 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.

The screenshot shows the IUCLID 6 web application interface. On the left, the 'Navigation panel' displays a search for 'Dossier' with 'Query type' set to 'Get all dossiers'. Below this is a table with one result:

Dossier Name	Subject Name	Creation date
RJS_MBER / SUBSTANCE: Test substance 1 / IUPAC_name / 2016-09-06 / Test dossier	Test substance 1	2016-09-06T10:16:07.956+03:00

A right-click context menu is open over the first row, with the 'Export' option highlighted. A red speech bubble points to the 'Export' option with the text: 'Your dossier is ready to be exported.'

The right side of the interface shows the 'Dossier header' and 'Dossier subject' details for the selected dossier. The 'Dossier header' includes fields for Name, Version, Dossier name, and Dossier subject. The 'Dossier subject' includes fields for Test substance, Submitting legal entity, Dossier creation date/time, and Dossier submission remark.

At the bottom right, the 'Information panel' shows the dossier's Type (Dossier), UUID (4434153b-6a71-497c-9e6f-e3f669f6a451), and Dossier UUID (4434153b-6a71-497c-9e6f-e3f669f6a451).

Export the dossier

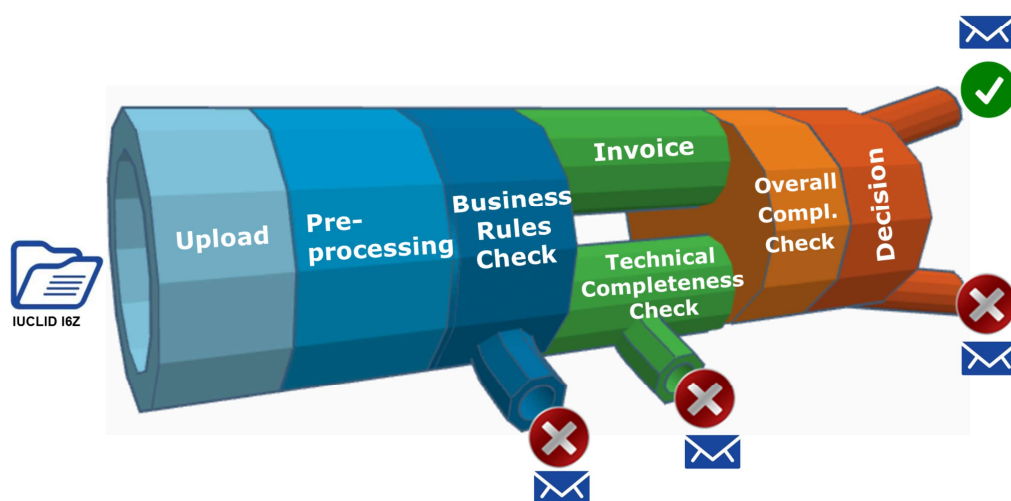
- Your dossier is ready to be exported from IUCLID and to be submitted to REACH-IT.

Regulatory processing



Regulatory processing

Regulatory processing by the Agency (1/2)



Regulatory processing by the Agency

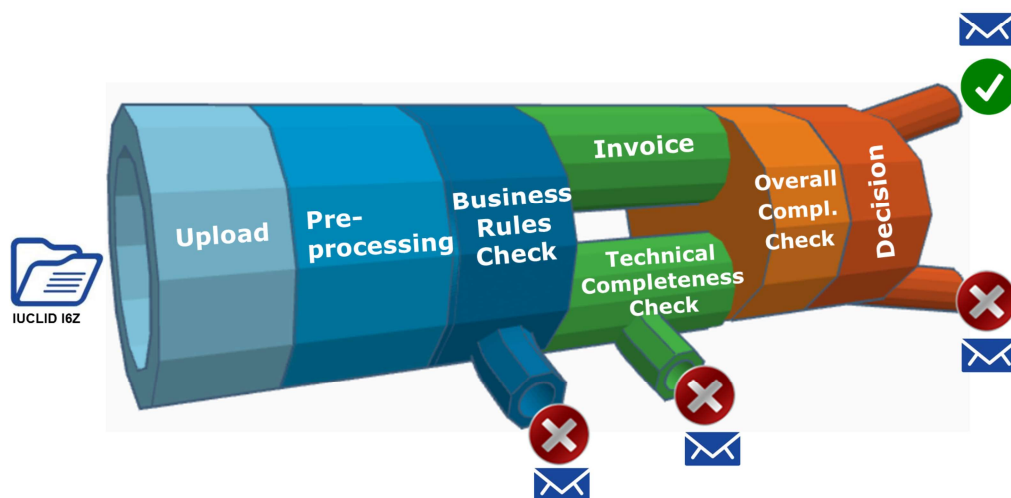
What happens to your registration dossier after submitting it to ECHA?

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.

Regulatory processing by the Agency (2/2)



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 initial 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: Outside 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.

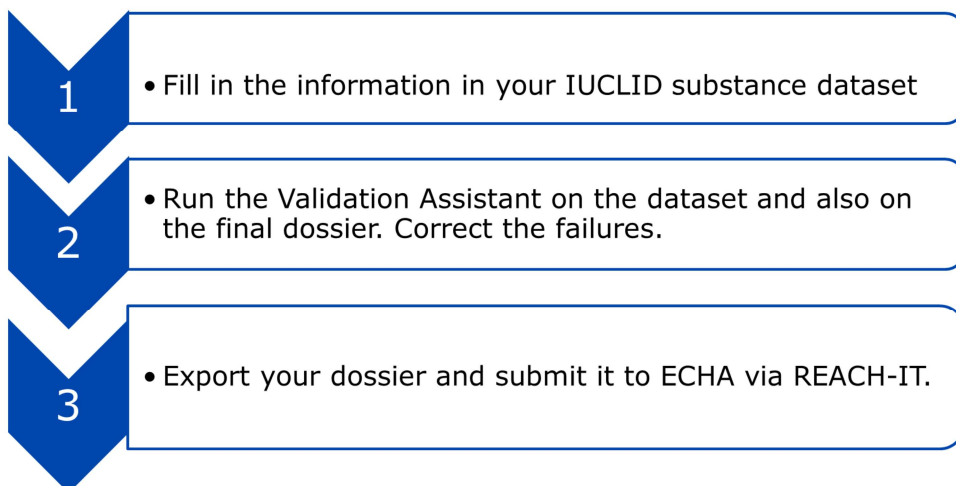
All these steps are communicated to the registrant via REACH-IT.

Summary



Summary

Creating a complete dossier in IUCLID



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



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>
- More information on the manual verification areas of the completeness check: https://echa.europa.eu/documents/10162/13652/manual_completeness_check_en.pdf
- Webinar on completeness check: <https://echa.europa.eu/-/completeness-check-preparing-a-registration-dossier-that-can-be-successfully-submitted-to-echa>

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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