

Dossier Quality Assistant

(Validation Assistant plug-in)

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Esther Callizo Viñuales
European Chemicals Agency



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Validation Assistant plug-in





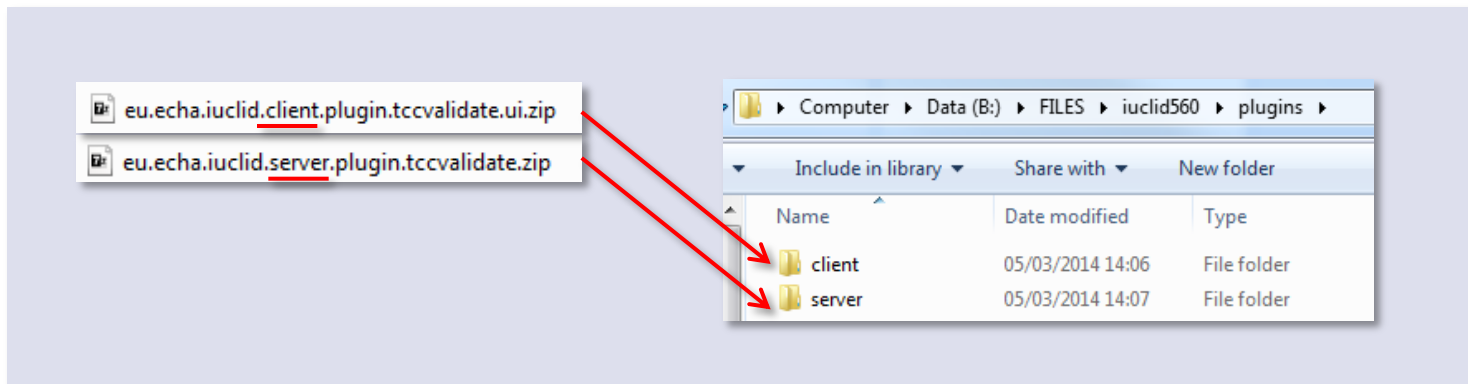
Validation Assistant plug-in

- IUCLID Validation Assistant plug-in supports companies in dossier preparation in their own IUCLID installations.
- Replaces former IUCLID Technical completeness check (TCC) plug-in.
- Modules:
 - Technical Completeness Check (TCC) rules
 - Business rules (BR)
 - Dossier Quality Assistant
 - **SID rules**
 - Quality rules



Validation Assistant plug-in

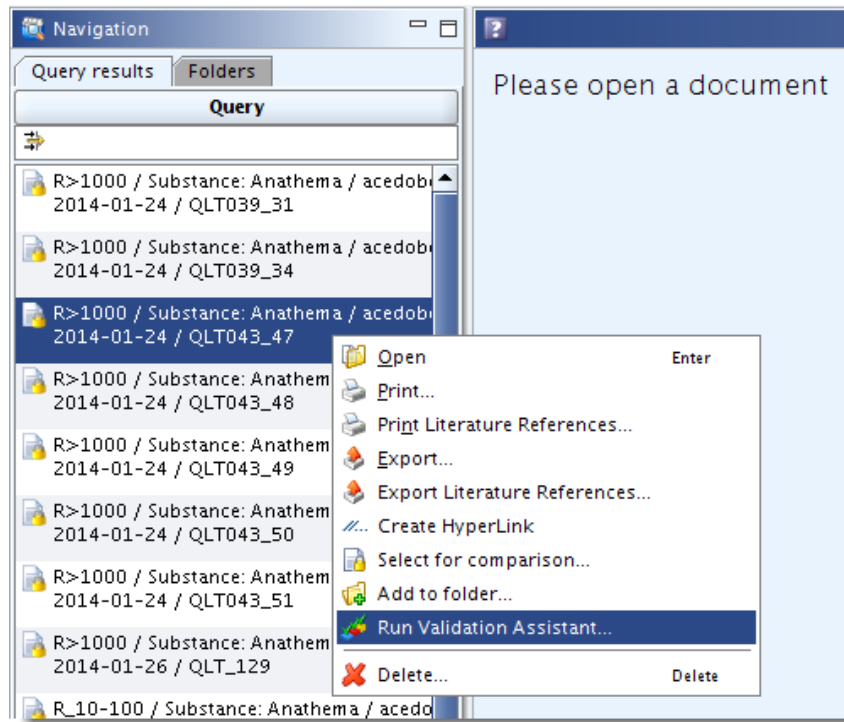
- Latest version is 5.4.4
 - available on IUCLID website iuclid.eu
 - compatible with IUCLID 5.4, 5.5, 5.6
- Easy to install
 - copy files into IUCLID installation folder





Validation Assistant plug-in

- Run plug-in on dossier or substance dataset





Validation Assistant plug-in

Validation Assistant

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 (1)
Technical Completeness Check
Dossier Quality Assistant

Filter: Show all with type failure, warning

Section number	Section name	Document name	Failure description	Type
Section 1.3	Identifiers		Failure in Business Rule BR040	BR failure
Section 1.3	Identifiers		You have identified your dossier as a spontaneous update but the given reference number (IUCLID 5 section 1.3) is not correct. Note, that the reference number must correspond to a registration/notification of the same dossier type as the update.	BR failure

Rules engine version: 7.02 Business rules version: 2.3.2 Completeness rules version: 2.2.8

1—2—3
Results

< Back Next > Finish Cancel

Dossier Quality Assistant





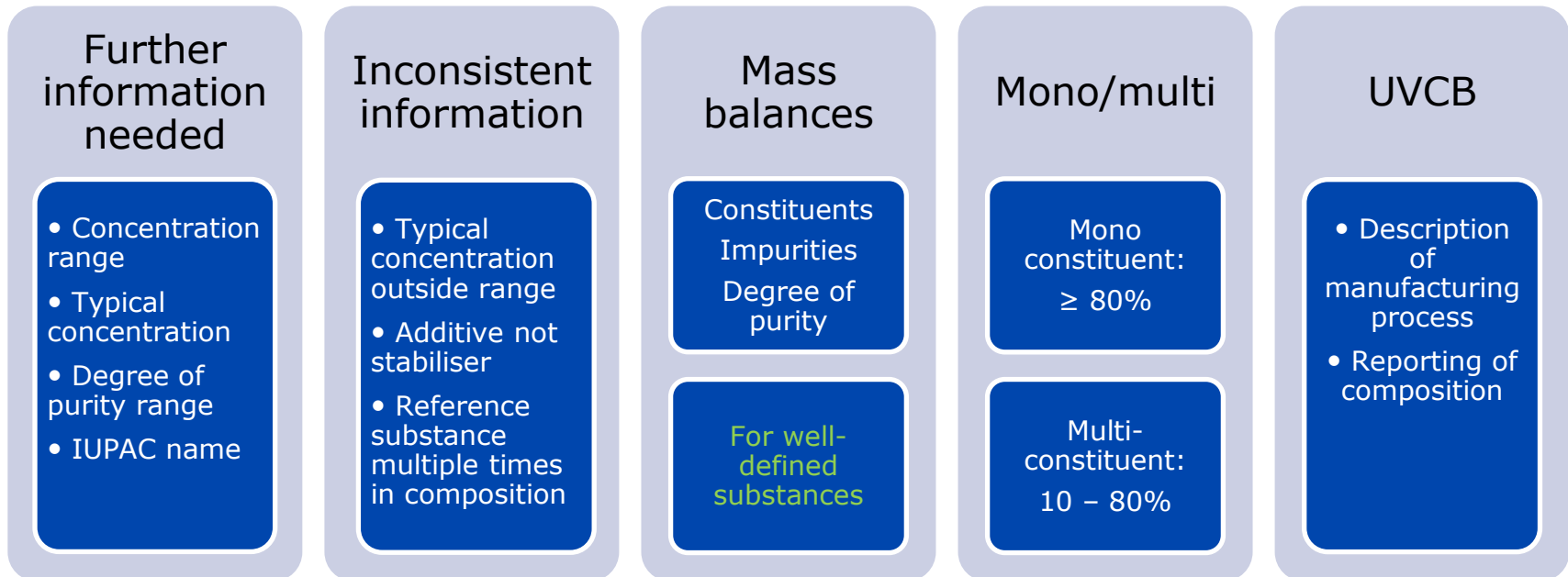
Dossier Quality Assistant

- DQA gives overview of ECHA quality findings and actions:
 - Common shortcomings from evaluation
 - Support screening campaigns (SID, intermediates)
- DQA not mandatory for submission, but:
 - Helps registrants resolving inconsistencies
 - We recommend to correct all related rules to make sure that you address the issue, because rules in the DQA are built based on information checked by other rules.










Dossier Quality Assistant – substance identity

- For REACH registrations and inquiry notifications
- The SID rule set covers the following types of issues:





SID rules supporting screening campaign

- Issue type 1: Missing concentration ranges 
- Issue type 2: Typical concentration outside of concentration range 
- Issue type 3: Composition reported with no constituents 
- Issue type 4: Low or ambiguous degree of purity for well-defined substances
- Issue type 5: Unidentified constituent or impurity present at significant concentration
- Issue type 6: Well-defined substance with inconsistency between degree of purity and constituent concentrations 
- Issue type 7: Well-defined substance with inconsistency between degree of purity and impurity concentrations 
- Issue type 8: No spectral and analytical information provided 
- Issue type 9: Additives without stabilising function 
- Issue type 10: Inconsistent identifiers of constituents, impurities and additives



Dossier Quality Assistant – key messages

- Substance identity rules in DQA support screening campaign:
 - Most issues can be checked with plug-in.
- DQA not mandatory for submission, but:
 - Helps registrants resolving inconsistencies and improving the quality of the dossier.
 - You are recommended to address all issues detected by the DQA, even if not mentioned in the screening letter.



Registrants should analyse the warnings given by the DQA to see if they apply to their situation - exceptions may exist!

Thank you

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