

IUCLID 5

Guidance and Support

IUCLID 5

Technical Completeness Check Plugin User Manual

IUCLID 5
INTERNATIONAL UNIFORM CHEMICAL INFORMATION DATABASE

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in association with the OECD

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1 Principle of the Technical Completeness Check (TCC) plugin

According to the REACH Regulation, registration dossiers and PPORD notifications are subject to a completeness check (Article 20(2)). This Completeness Check can be divided in two parts: the Financial Completeness Check (FCC) and the Technical Completeness Check (TCC).

The aim of the Technical Completeness Check (TCC) plugin is to enable registrants and PPORD notifiers to check within their IUCLID 5 installation (or database) the technical completeness of their dossiers (or datasets) prior a submission to ECHA via REACH-IT. The plugin also checks that the dossier (or substance) will be able to pass some of the business rules.

Please note that although the tool simulates the technical completeness check carried out by ECHA to the largest extent possible, it will not be able to capture exhaustively all possible scenarios in which a dossier may be found incomplete (e.g. resulting from the combination of lead and member dossiers in a joint submission). In addition, as some of the business rules depend on information that is within the REACH-IT database, the plugin cannot simulate all the currently existing business rules. The responsibility remains with the company ensure that their submission fulfils all the relevant legal requirements.

Please, refer to Data Submission Manual 5 “How to complete a technical dossier for registrations and PPORD notifications” for detailed information on how to fill in the minimum requirements in IUCLID 5. The manual is available at http://echa.europa.eu/reachit/dsm_en.asp.

2 Adding the plugin to your local IUCLID 5 installation

The plugin is based on a server side and a client side ZIP file called:

- eu.echa.iuclid.**server**.plugin.tccvalidate.zip
- eu.echa.iuclid.**client**.plugin.tccvalidate.ui.zip

The installation of the plugin depends on your IUCLID 5 installation:

- workstation / stand-alone version or
- distributed version

2.1 Workstation / stand-alone installation

If you have installed the IUCLID 5 stand-alone software in the folder


C:\IUCLID5

You will find the sub-folders:

C:\IUCLID5\plugins\client (folder for the client side plugins)

C:\IUCLID5\plugins\server (folder for the server side plugins)

To install the plugin you need to copy the above-mentioned client and server side zip-files into the appropriate folders (see examples below in the table).

 **Please note** that for the plugin to work properly, both of the zip-files must be copied into their respective folders – it is not enough to copy only the client side zip-file.

Important:

Do not extract the ZIP files!
Depending on your computer setting the file name may be displayed without extension (.zip).

Copy the file	eu.echa.iuclid. client .plugin.tccvalidate.ui.zip
into the folder	<IUCLID5-folder>\plugins\client
Sample	C:\IUCLID5\plugins\client\eu.echa.iuclid.client.plugin.tccvalidate.ui.zip
Hint	In the folder you will already find files like: <ul style="list-style-type: none"> - clientExtensionPointRootPlugin.zip - eu.echa.iuclid.plugin.helpsystemEN.zip - eu.echa.iuclid.plugin.xform.zip

Copy the file	eu.echa.iuclid. server .plugin.tccvalidate.zip
into the folder	<IUCLID5-folder>\plugins\server
Sample	C:\IUCLID5\plugins\server\eu.echa.iuclid.server.plugin.tccvalidate.zip
Hint	In the folder you will already find files like: <ul style="list-style-type: none"> - serverExtensionPointRootPlugin.zip - eu.echa.iuclid.plugin.resources.zip

The plugin will be available after **re-starting your IUCLID 5 application**.

Tip:

If the plugin is no longer required, the files can be removed from the folders. The plugin will disappear from the IUCLID 5 application.

2.2 Distributed installation

You will find the sub-folders on your IUCLID 5 application server:

- ...\\i5clientPlugins\\remotePlugins (folder for the client side plugins)
- ...\\WEB-INF\\classes\\plugins (folder for the server side plugins)

To install the plugin you need to copy the above-mentioned client and server side zip-files into the appropriate folders (see examples below in the table).

Important:

Do not extract the ZIP files!
Depending on your computer setting the file name may be displayed without extension (.zip).

Copy the file	eu.echa.iuclid. client .plugin.tccvalidate.ui.zip
into the folder	<IUCLID5 WebApp-folder> i5clientPlugins\\remotePlugins
Sample	C:\\Program Files\\apache-tomcat-5.5.20\\webapps\\i5server\\i5clientPlugins\\remotePlugins\\eu.echa.iuclid.client.plugin.tccvalidate.ui.zip
Hint	In the folder you will already find files like: <ul style="list-style-type: none"> - clientExtensionPointRootPlugin.zip - eu.echa.iuclid.plugin.helpsystemEN.zip - eu.echa.iuclid.plugin.xform.zip

Copy the file	eu.echa.iuclid. server .plugin.tccvalidate.zip
into the folder	<IUCLID5 WebApp-folder> WEB-INF\\classes\\plugins
Sample	C:\\Program Files\\apache-tomcat-5.5.20\\webapps\\i5server\\WEB-INF\\classes\\plugins\\eu.echa.iuclid.server.plugin.tccvalidate.zip
Hint	In the folder you will already find files like: <ul style="list-style-type: none"> - serverExtensionPointRootPlugin.zip - eu.echa.iuclid.plugin.resources.zip

The plugin will be available after **re-starting your IUCLID 5 application as well as your server (e.g. TOMCAT).**

Tip:

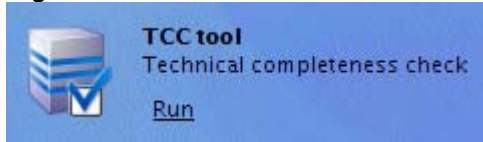
If the plugin is no longer required, the files can be removed from the folders. The plugin will disappear from the IUCLID 5 application.

3 Launching the TCC Tool

After the installation of the plugin the new functionality is available in IUCLID 5:

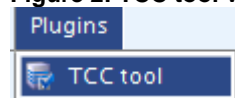
- In the task pane, in the part “Plugins”

Figure 1: TCC tool run button



- In the main menu of IUCLID 5

Figure 2: TCC tool via menu item



- In the toolbar

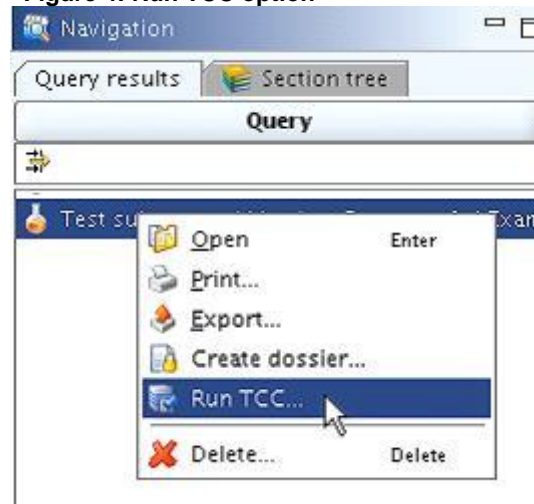
Figure 3: TCC Toggle button



A click on this toggle button in the toolbar hides or displays the TCC window, e.g. it allows the user to modify a substance dataset without losing the settings defined for the TCC check.

- In the ‘Query’ window of your list of dossiers or substances


Figure 4: Run TCC option



In the ‘Substance’ or ‘Dossier’ menu, right-click the name of the substance dataset or dossier in the ‘Query’ window, and select ‘Run TCC’. This is a convenient way to launch the completeness check of the substance dataset or the dossier right after modifying/creating it without having to search for it. Furthermore, since the completeness check can be launched from the same location where dossier creation (in the case of a substance dataset) or dossier export (in the case of a finished dossier) takes place, the possibility of checking the incorrect substance/dossier is reduced.

4 Using the TCC tool

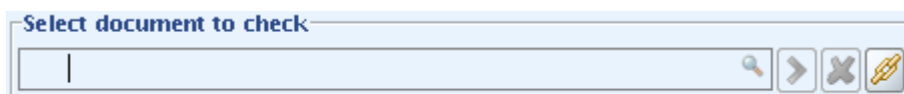
This section explains how to use the TCC tool to check the completeness of a dossier or a substance dataset.

Click on  in the Task pane to go Home if you are not already there. Start the TCC tool wizard as described above.

4.1 STEP 1: select the dossier/substance

The first step in the wizard is to choose the document used for the TCC by clicking on the  icon.

Figure 5: Entry field 'Select document to check'



This will open a query window where it will be possible to select either a dossier or a substance (the TCC plugin can be used to check the completeness of dossiers or of substance datasets).

Figure 6: Query selection



4.1.1 Checking dossiers

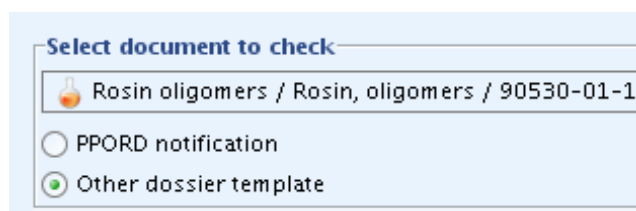
The TCC plugin will by default perform the Technical Completeness Check applying the rules for the dossier template used in the creation of the dossier.

⚠ Important note: It is strongly recommended to run the TCC plugin on the final dossier prior to submitting it in REACH-IT.

4.1.2 Checking substance datasets

Unlike dossiers, substance datasets do not correspond to a specific type of REACH registration, therefore the user needs to select which rules need to be applied for the TCC. If the substance has to be checked in order to create a PPORD notification dossier, tick the radio button "PPORD notification". Otherwise let the box "Other dossier template" ticked (selection done by default) and when you press the "Next" button you will be directed to a new screen where you can select for what kind of registration dossier you would like to perform the TCC (see Step 2 below).

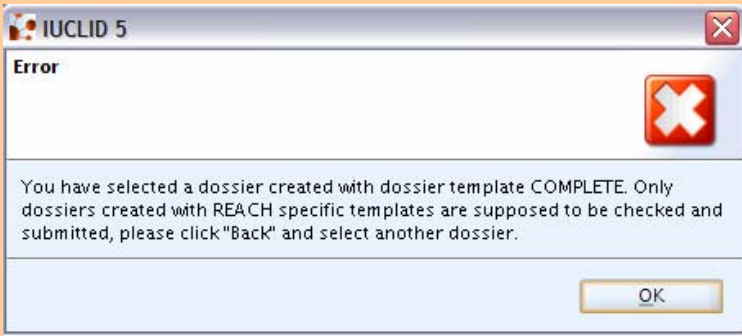
Figure 7: Radio button for dossier type



⚠ Important note: A IUCLID 5 dossier consists of two parts: a substance dataset, and the so called dossier header. The dossier header has to be generated during the dossier creation process, and it contains certain relevant information about the dossier, such as the tonnage band covered by the registration. The Technical Completeness Check also verifies the presence of certain information in the dossier header. However, this information can only be checked for dossiers, since a substance dataset does not contain a dossier header. Therefore, even if your substance dataset is considered complete by the plugin, it is strongly recommended that you check also the dossier you have generated from the substance dataset to verify that the dossier header is also complete.

Important:

Please keep in mind that this tool has been designed to validate the technical completeness of REACH registration dossiers and PPORDs. In addition, the REACH templates for CPL notification, Inquiry, Downstream user report, and Notification of substance in article, are supported for business rules check. If the validation is started on a dossier created with another dossier template the process aborts with an error similar to the one shown below:



The user must also define if the dossier is for a phase-in or for a non phase-in substance. If the user wants to claim a fee waiver, this must also be indicated. By default, the settings of the plugin are for a phase-in substance with no fee waiving claimed. In addition, to check that the relevant ‘Regulatory programme identifiers’ are entered in IUCLID 5 section 1.3, the user should indicate the update status of the dossier to be submitted

Note: the fee waiver can only be claimed in the case stated in REACH Article 74(2).

Figure 8: Selection of phase-in definition, fee waiving and update status

Phase-in definition (not applicable to PPORD notifications)

Phase-in substance Non phase-in substance

Fee waiving (not applicable to PPORD notifications)

Yes No

Submission update (indicate reason for submission update, if applicable)

Is the submission an update?

Spontaneous update

Once all the necessary definitions are done the user can proceed to the next step by clicking on the “Next” button. If you select “Other dossier template”, you will be directed to step 2 (where further parameters need to be specified). If you select “PPORD notification” you will be directed directly to step 3 (where the TCC results are displayed).

4.2 STEP 2: select the template (only for substance datasets)

In this step the user has to define which template should be used for the TCC, i.e. the tonnage band of the registration dossier, if it is part of a joint submission and if it covers intermediate uses or not. After these parameters are defined, the “Next” button becomes active.

4.2.1 Combined dossier

A combined dossier refers to the case where a registration covers both the use of a substance as an intermediate as well as non-intermediate use. If you are in this situation, and your dossier is not part of a joint submission, tick the radio button “No” in the block “Joint submission” and then use the picklists “Registration dossier” and “Intermediates” to select the relevant tonnage bands for both cases.

Figure 9: TCC selection for tonnage band

4.2.2 Lead of a joint submission

If you are preparing the lead dossier for a joint submission, tick the radio button “Yes” in the block “Joint submission”. The block “Role in the joint submission” will appear. Set the radio buttons to “Lead registrant of a joint submission” and then select the tonnage band for your dossier. You can make a selection in both picklists (“Registration dossier” and “Intermediates”) if you have both uses covered in your dossier.

Figure 10: TCC selection for a lead dossier

Technical completeness check

The European Chemical Agency (ECHA) has developed this plug-in to assist legal entities in verifying the Technical Completeness Check (TCC) of a dossier or a substance dataset according to Article 9(3) or 20(2) of the REACH Regulation.

Joint Submission

No Yes

Role in the Joint submission

Member of a joint submission
 Lead registrant of a joint submission
 The lead registrant should select here below the dossier type that refers to the joint submission dossier.

In general only one dossier type must be selected, either in the picklist "Registration dossier" or in the picklist "Intermediate". In exceptional case where the registrant would like to submit a combined dossier which would cover a standard registration as well as an intermediate use, then an item in both picklists must be selected.

Registration dossier: 10 - 100 tonnes

Intermediates: not applicable

1 — 2 — 3
Define dossier options

< Back Next > Finish Cancel

4.2.3 Member of a joint submission

Tick the radio button “Yes” in the block “Joint submission”. Set the radio button to “Member of a joint submission” and then select the tonnage band for your dossier. You can make a selection in both picklists (“Registration dossier” and “Intermediates”) if you have both uses covered in your dossier. You should also indicate if the “Chemical Safety Report” and “Guidance on safe use” are provided by your lead on your behalf or if they are included in your dossier.

Please note also that you should make a selection in the picklist “Tonnage band of the joint submission”.

⚠ Note: for the endpoint sections (section 4 to 8 of IUCLID 5) a dossier for a member of a joint submission should normally contain only endpoint study records for those endpoints for which you opted out from the joint submission. In the same manner, the member dossier should not contain any C&L block (IUCLID 5 section 2) unless the member indicated that he is opting out for the C&L.

Figure 11: TCC selection for a member dossier

Technical completeness check

The European Chemical Agency (ECHA) has developed this plug-in to assist legal entities in verifying the Technical Completeness Check (TCC) of a dossier or a substance dataset according to Article 9(3) or 20(2) of the REACH Regulation.

Joint Submission

No Yes

Role in the Joint submission

Member of a joint submission

Tonnage band of the joint submission: Registration dossier above 1000 tonnes

Tonnage band of the member

Tonnage band (standard registration): Between 100 to 1000 tonnes/year

On-site isolated intermediate tonnage band:

Transported isolated intermediate tonnage band:

Provided by lead

Guidance on safe use Chemical Safety Report

Lead registrant of a joint submission

In general only one dossier type must be selected, either in the picklist "Registration dossier" or in the picklist "Intermediate". In exceptional case where the registrant would like to submit a combined dossier which would cover a standard registration as well as an intermediate use, then an item in both picklists must be selected.

Registration dossier: not applicable

Intermediates: not applicable

Define dossier options

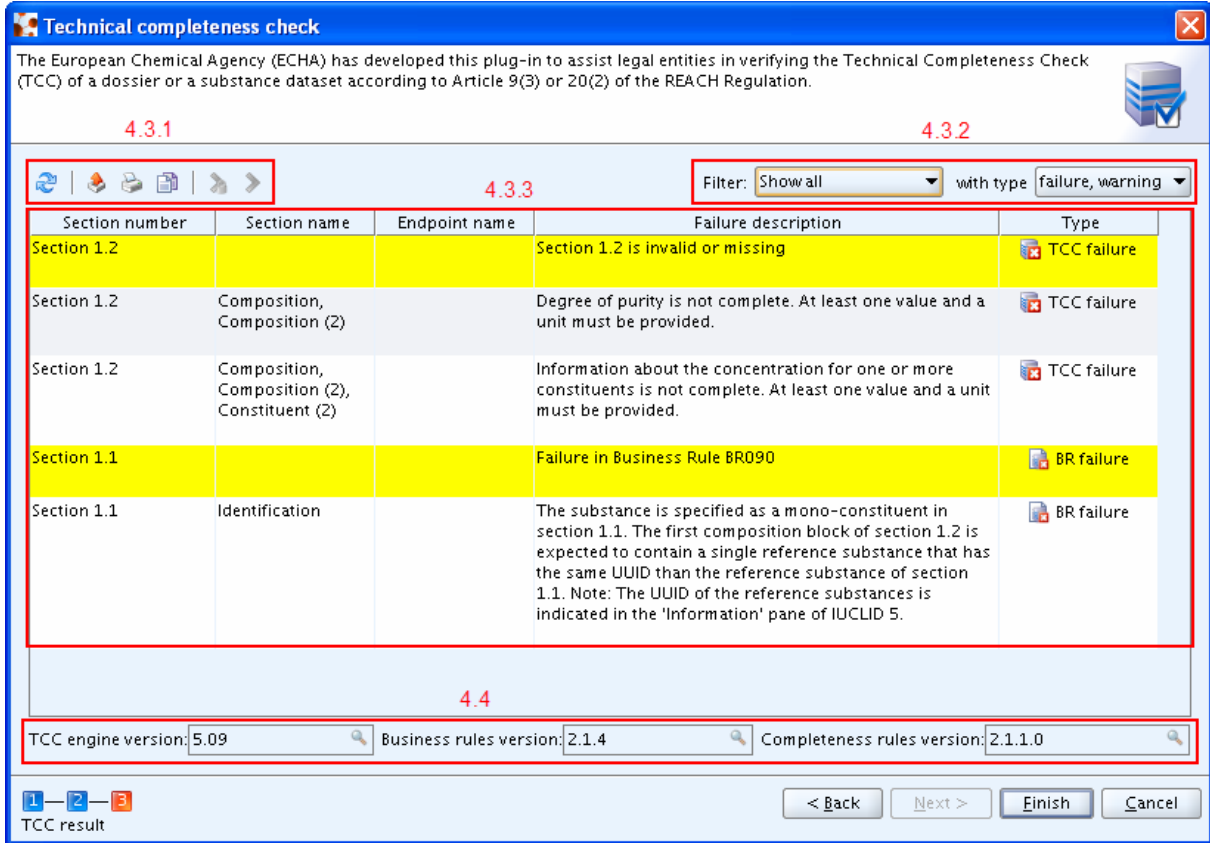
< Back Next > Finish Cancel

After having completed this screen the “Next” button becomes active. Clicking on this “Next” button will run the TCC and display the results on Step 3.






4.3 STEP 3: TCC results and interpretation


On this step the result for the TCC is displayed. The different parts of the result display screen are further described in the following subsections.

Figure 12: TCC results page





4.3.1 TCC results toolbar





-  Refresh the TCC result (only for substance datasets)
-  Export the result list as xml. All the TCC results are exported in a XML file.
-  Print the TCC result
-  Copy the TCC results (could be pasted to Excel, Word...)
-  Navigate to the document in the dossier

If you select any row and press this button, it will open the dossier which was checked at the corresponding section.
-  Navigate to the document in the substance dataset

If you select any row and press this button, it will open the substance which was checked (or the one that was used to create your dossier) at the corresponding section. This option is not available if you were checking a dossier but the substance dataset that was used to generate that dossier is not in your IUCLID 5 database.

Tip: A double click on any row of the TCC results table has the same effect than clicking on the navigation buttons  and . As a consequence a double click on a specific row will directly open the substance/dossier at the corresponding section.

4.3.2 Filtering the results table

Show all	All result items are displayed without filtering.
Only TCC rules	Only results with the level “TCC failure” () and “TCC warning” () are displayed in the results table
Only Business rules	Only results with the level “BR failure” () and “BR warning” () are displayed in the results table
Failure, warning	Both failures and warnings are displayed in the results table.
Failure	Only the failures are displayed in the results table, not the warnings.

When a dossier or substance is run through the TCC plugin, there are four types of messages that are displayed: Business Rules warnings, Business Rules failures, Technical Completeness Check warnings and Technical Completeness Check failures.

BR warnings

A BR warning does not directly translate to a BR step failure in REACH-IT, but it informs you of some information that should normally be in your dossier. Therefore, you are advised to correct the issue that raised the warning message, since it could have implications for the compliance of your dossier.


BR failures

A BR failure in the plugin is associated with a BR step failure in REACH-IT. If you submit a dossier without correcting the issue mentioned in the message, your dossier will fail the business rules check during the submission process.

TCC warnings

A TCC warning is not an indication of that your dossier will fail the TCC, but it informs you of some information that should normally be in your registration dossier. Therefore, you are advised to correct the issue that raised the warning message, since it could have implications for the compliance of your dossier.

TCC failures

These messages correspond to the Technical Completeness Check. If you do not correct the issue mentioned in one of these messages, your dossier will fail the TCC in REACH-IT. These messages are flagged with the  icon.

4.3.3 TCC results table

The rows highlighted in yellow in the TCC results table indicate the sections of the dossier/substance that gave rise to the failure/warning.

Figure 13: Yellow rows of the TCC results table

The screenshot shows a table with the following data:

Section number	Section name	Endpoint...	Failure description	Type
Section 1.2			Section 1.2 is invalid or missing	TCC failure
Section 1.2	Composition, Composition (2)		Degree of purity is not complete. At least one value and a unit must be provided.	TCC failure
Section 1.2	Composition, Composition (2), Constituent (2)		Information about the concentration for one or more constituents is not complete. At least one value and a unit must be provided.	TCC failure

The rows in grey or white indicate the fields of the dossier/substance that need to be filled in to correct the failure/warning.

Figure 14: Grey/white rows of the TCC results table




The screenshot shows the same table as Figure 13, but with the second and third rows highlighted in grey:

Section number	Section name	Endpoint...	Failure description	Type
Section 1.2			Section 1.2 is invalid or missing	TCC failure
Section 1.2	Composition, Composition (2)		Degree of purity is not complete. At least one value and a unit must be provided.	TCC failure
Section 1.2	Composition, Composition (2), Constituent (2)		Information about the concentration for one or more constituents is not complete. At least one value and a unit must be provided.	TCC failure

A right mouse click on the results table opens the following menu:

Print table	The whole TCC result table will be printed.
Copy table	The whole TCC result table will be copied in the windows clipboard and could be pasted in Excel or Word for instance.
Go to referenced document (dossier data)	This option will open the dossier that was checked with the plugin.
Go to referenced document (raw data)	This option will open the substance dataset that was checked with the plugin (if available in your IUCLID 5 database).

Tip: At step 3 of the TCC plugin (results table), if you are running the TCC on a substance dataset, it is possible to interactively correct/modify the dataset while keeping the TCC results table open. After obtaining the TCC results table in step 3:

- Click on the toggle button  to hide the TCC plugin window, or move the plugin window aside
- Correct the indicated failure in the substance dataset
- Click on the save button  in the IUCLID 5 toolbar
- Click on the toggle button to show the TCC plugin window
- Click on the refresh button  of the TCC plugin window to see if the failure description is still present.

Specific cases where failures indicated by the TCC plugin may be disregarded:

There are cases where a TCC failure is listed in the TCC result table even if the dossier may be technically complete. These TCC failures do not mean that the dossier will necessarily fail the TCC but that a manual intervention will be needed from ECHA side in order to verify completeness. This is the case, for instance, with the following TCC failure:

- Dossier header: You are a member of a joint submission and your dossier contains an opt-out. If your tonnage band is higher than the tonnage band of the joint submission then ECHA will check that your additional information requirements have been fulfilled. If your tonnage band is not higher than the tonnage band of the joint submission then this message can be disregarded.

When no TCC/BR failures are found in the dossier or the substance dataset, this is reported by the following TCC/BR warning messages:

- TCC: 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.
- BR: 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.

⚠ Note: When updating a registration that was previously a notification under Directive 67/548/EEC for another reason than a tonnage band update, less information is required than for a standard dossier. The minimum information to be provided in this case is described in Annex 4 of Data Submission Manual 5 “How to complete a technical dossier for registrations and PPORD notifications”. However the TCC plugin does not offer the possibility to check automatically the completeness of these specific dossiers. As a consequence, the TCC plugin can be used to check the completeness of these dossiers but only the TCC failures/warnings related to the information requirements indicated in Annex 4 of Data Submission Manual 5 could be a reason for considering the dossier as incomplete. The manual is available at http://echa.europa.eu/reachit/dsm_en.asp.

4.4 TCC version information

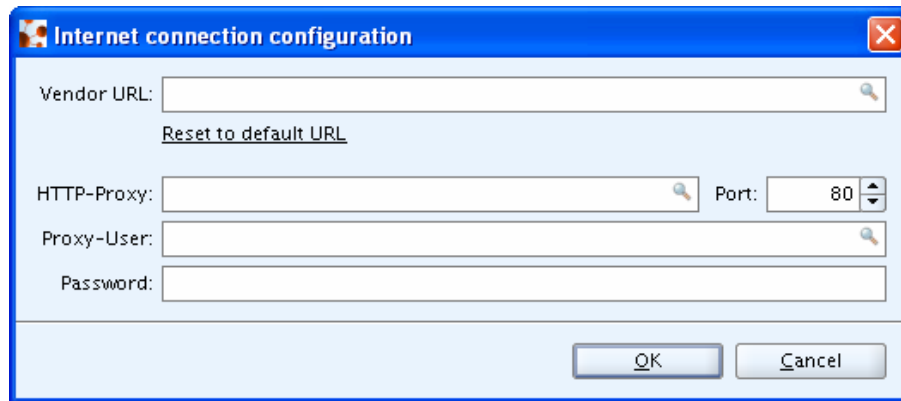
When launching the TCC plugin, in step 1 there is a plugin version checker at the bottom of the plugin window. The version checker verifies the version of the currently installed TCC plugin and displays a warning message if a newer version is available on the IUCLID 5 website. To get the version checker working an internet access needs to be established. In case a proxy server is necessary for the internet access this can be defined by pressing the plugin checker button:

Figure 15: Message for failed version check



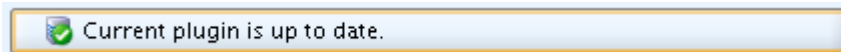
Afterwards a configuration popup window will appear where you will be able to define, if necessary, a proxy hostname and a port. The vendor URL is the URL from the IUCLID 5 website which is used for the online check. The definitions are stored for each user on the server. To reset the default value for the vendor URL just press “Reset to default URL” below the vendor URL input field.

Figure 16: Internet connection configuration



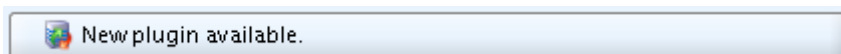
If the plugin is up to date the following status is displayed:

Figure 17: Message for plugin up to date



If a newer TCC plugin is available for update the following status is displayed:

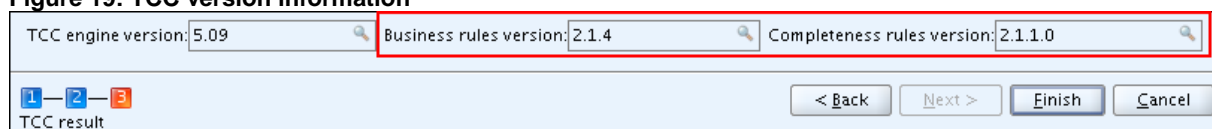
Figure 18: Message when new plugin is available



In this last case the new TCC plugin should be downloaded from the IUCLID 5 website (the previous one needs to be removed and the new one installed).

In step 3 of the TCC plugin, below the TCC result table the version information for the TCC engine, the used business rules version and the completeness check rules version are displayed. In order to verify that you are using the latest version of the TCC plugin, you may compare these version numbers with the ones listed on the download page of the TCC plugin found on the IUCLID 5 homepage.

Figure 19: TCC version information



European Chemicals Agency

IUCLID 5 Support

Technical Completeness Check plugin Manual
April 2011 v 1.2

<http://iuclid.eu>

