Hands-on exercise

With key

Contents

1. Intro

This exercise material aims to give you your first contact with IUCLID 6 and the Validation assistant prior building your registration dossier for the REACH 2018 registration deadline. It is recommended to read the presentation first (about one hour) and then to continue with the exercise (about one hour). The exercise instructions are followed by the key. The key provides you with technical advice on how to complete the exercise; it does not provide regulatory advice. Note that the training substance dataset does not include real data and it should not be taken as a model for meeting the REACH requirements.

For the exercise you will need IUCLID 6. You may go to the IUCLID 6 website, sign-up/log-in and download the IUCLID 6 desktop version. See https://iuclid6.echa.europa.eu/.

Alternatively, you may use the IUCLID Cloud Trial service which is accessible via the ECHA website at https://echa.europa.eu/support/dossier-submission-tools/echa-cloud-services. You can log-in online with your ECHA account credentials (same as for your REACH-IT account) and subscribe to the IUCLID Cloud Trial service. In order to participate in this exercise using IUCLID cloud, please click on the IUCLID icon in the bottom left corner of the dashboard page of IUCLID cloud. This will launch the IUCLID client version, i.e. the look and feel will be the same as of the desktop IUCLID, and you will be able to follow the screenshots of this exercise key.
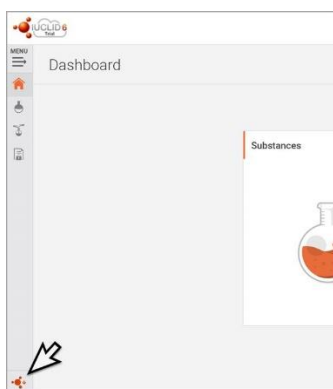

2. Instructions

2.1. Legend

You are the Lead registrant of the ECHA_TrainingSubstanceX. The joint registration covers the tonnage band of 10-100 t/y. Also your own manufactured tonnage of this substance is 10-100 t/y. You as lead registrant provide the Guidance on Safe Use (GSU in IUCLID section 11) and the Chemical Safety Report (CSR in IUCLID section 13) on behalf of the members of the joint submission.
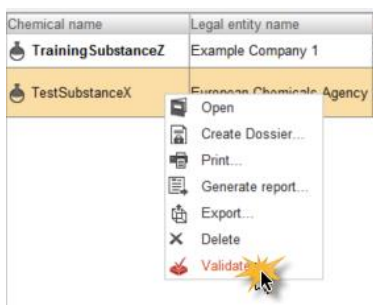
2.2. Exercise step by step

STEP 1: Launch IUCLID 6 and import the training substance file (.i6z format)
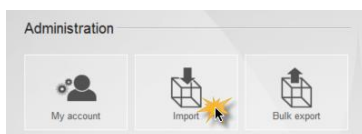
STEP 2: Find your substance

STEP 3: Run the Validation assistant on your substance dataset and correct all the reported submission errors

STEP 4: Make sure there is no submission failures remaining. Create your dossier. Fill in the dossier header information according to the legend provided in the beginning of the exercise.
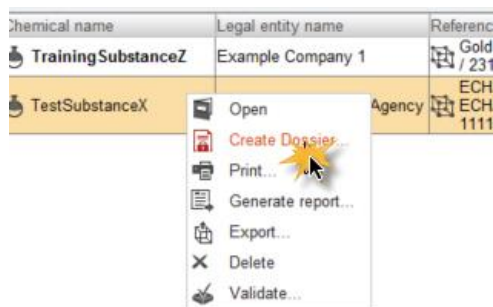
STEP 5: Run the Validation assistant on your final dossier to verify that no submission failures have remained.

> ➢ If the Validation assistant still shows errors: go back to your substance dataset, correct the errors and then create a new dossier.
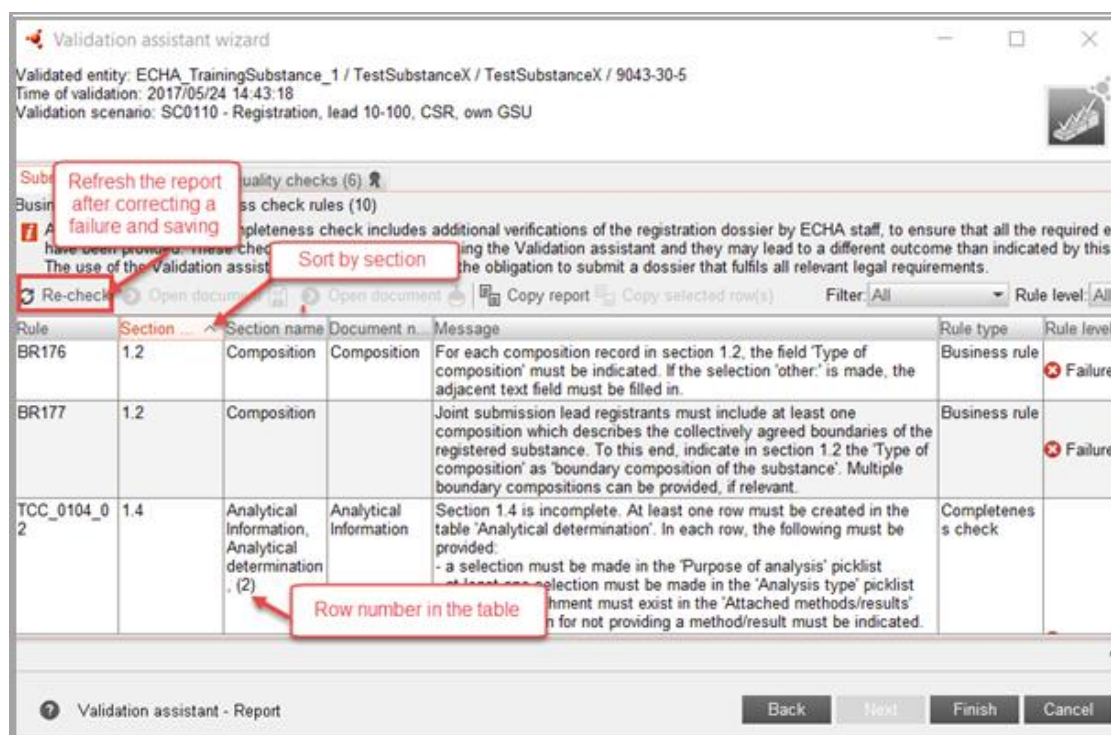
> ➢ If the Validation assistant does not report any errors: export your dossier and save it in your computer.

Your training dossier is now ready!
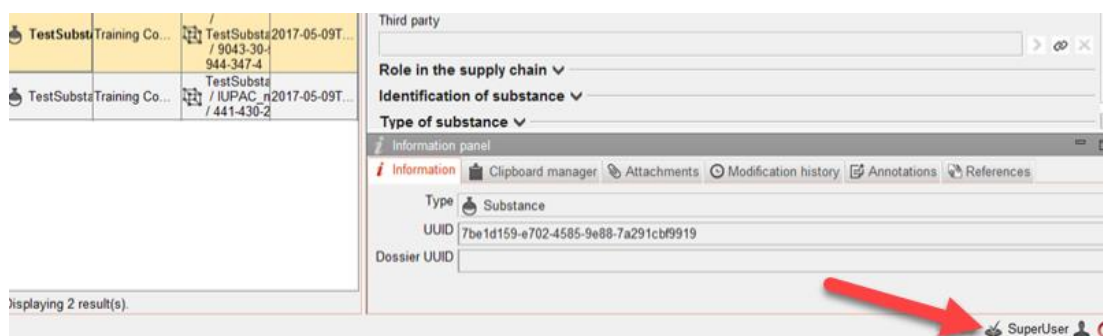
3. Key to the exercise

The following solutions provide only technical advice on how to correct the submission errors. The explanations why certain information is required are not in the scope of this training material but can be found in the ECHA manual "How to prepare registration and PPORD dossiers" at https://echa.europa.eu/manuals.

3.1. Tips for using the Validation assistant

After correcting a failure, click on the 'save' icon in IUCLID and refresh the Validation assistant report by clicking on the re-check button (shown on the screenshot above). If the failure was corrected as required then the respective failure message has disappeared from the report.

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

3.2. Failure BR176 and BR177

Comment: Correcting BR177 also corrects BR176

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	❌ Failur
BR176	1.2	Composition	Composition	For each composition record in section 1.2, the field 'Type of composition' must be indicated. If the selection 'other:' is made, the adjacent text field must be filled in.	Business rule	❌ Failur

3.2.1. How to correct?

STEP 1: In this exercise you are lead registrant and therefore you need two composition records in IUCLID section 1.2: one marked as "legal entity composition of the substance" and second marked as "boundary composition of the substance". This second composition record is to describe the boundaries of the joint registration.

These business rules errors indicate that you need to make a selection in the field 'Type of composition' in the second composition record and select "boundary composition of the substance".


3.3. Failure TCC_0104_02

| TCC_0104_02	1.4	Analytical Information, Analytical determination, (2)	Analytical Information	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 picklist fields, the adjacent text field must be filled in.	Completeness check	❌ Failure

There is something wrong or missing in the second row of the table 'Analytical determination'

3.3.1. How to correct?

STEP 1: Select row 2 of the table 'Analytical determination' and click Edit
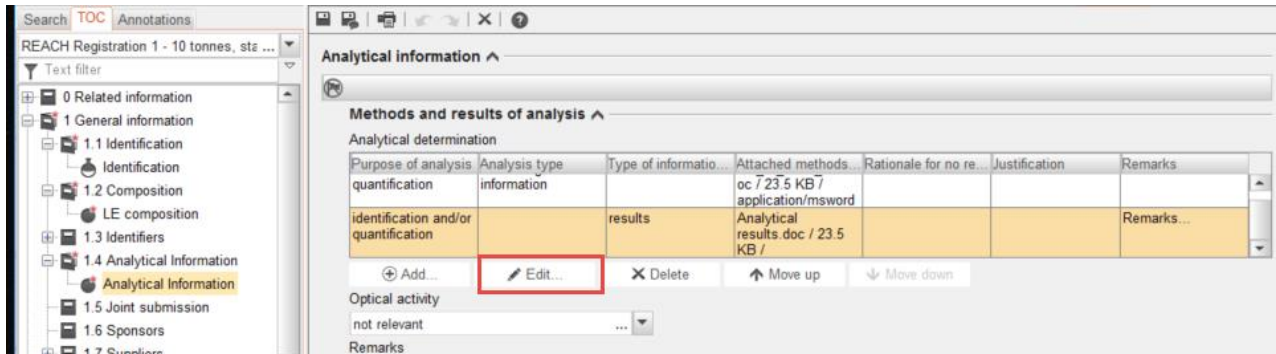
STEP 2: Make a selection from the drop down list 'Analysis type'
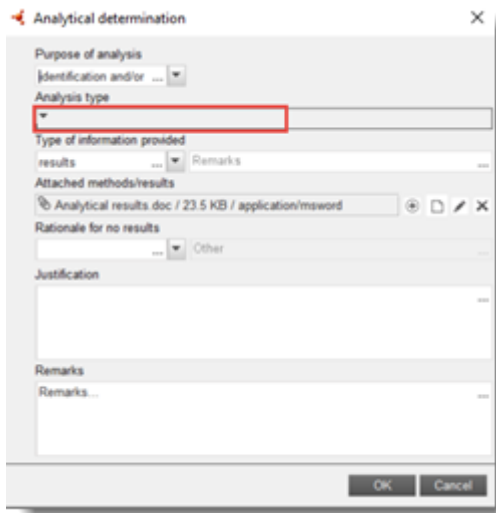
3.4. Failure BR049 and TCC_0303_01

**Comment:** Correcting BR049 corrects also the TCC_0303_01 and the other way around

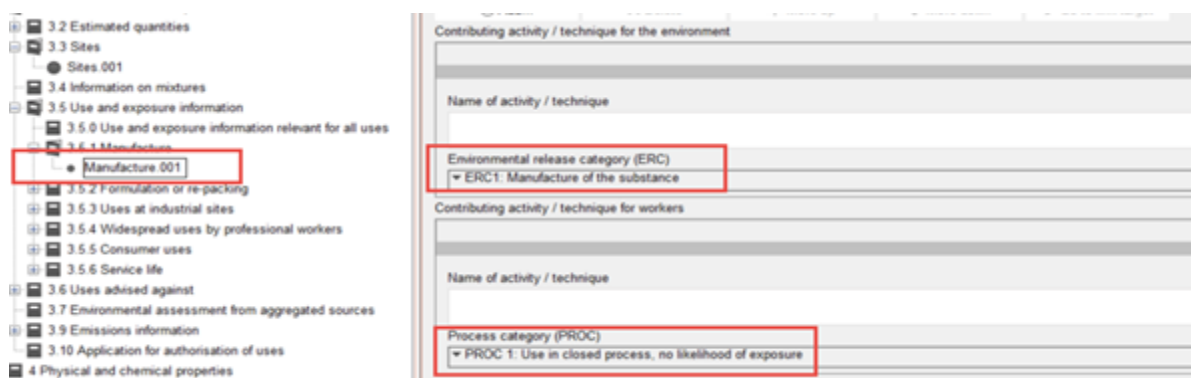| TCC_0303_01 | 3.3 | Sites | Sites.001 | If you indicated in section 1.1 that your 'Role in the supply chain' is 'Manufacturer', then you must provide at least one production site in section 3.3. To this end, you must create a record in section 3.3 and link a 'Site' to it. The contact address of each site must be provided; as a minimum the fields 'Site name', 'Address', 'Town' and 'Country' must be filled in. In addition, to indicate the site as a production site, you must link it using the field 'Related manufacture/own use' to at least one manufacture record in section 3.5.1. | Completeness check | ❌ Failure |
| BR049 | 3.3 | Sites | | If you indicated in section 1.1 that your 'Role in the supply chain' is 'Manufacturer', then you must provide at least one production site in section 3.3. To this end, you must create a record in section 3.3; link a 'Site' to it; and link it using the field 'Related manufacture/own use' to at least one manufacture record in section 3.5.1. | Business rule | ❌ Failure |

3.4.1. How to correct?
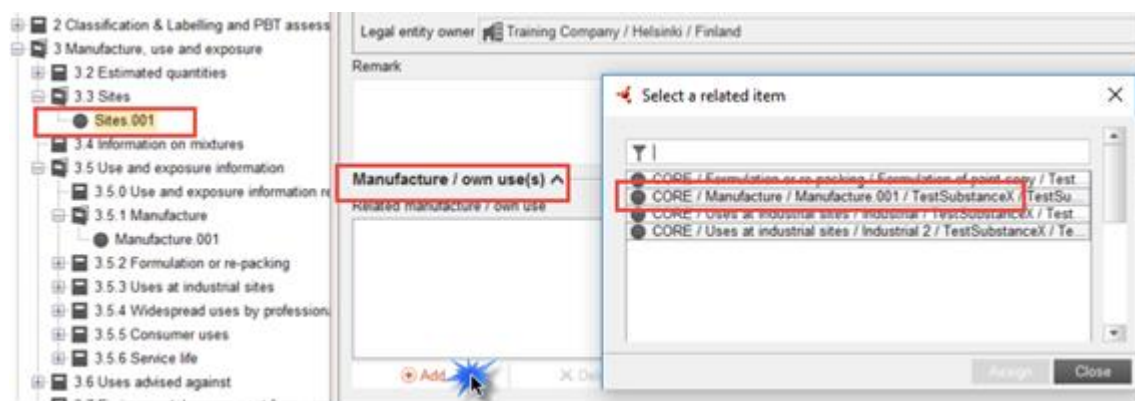
STEP 1: Create a new record in section 3.5.1

STEP 2: As a minimum fill the fields Manufacture name and …
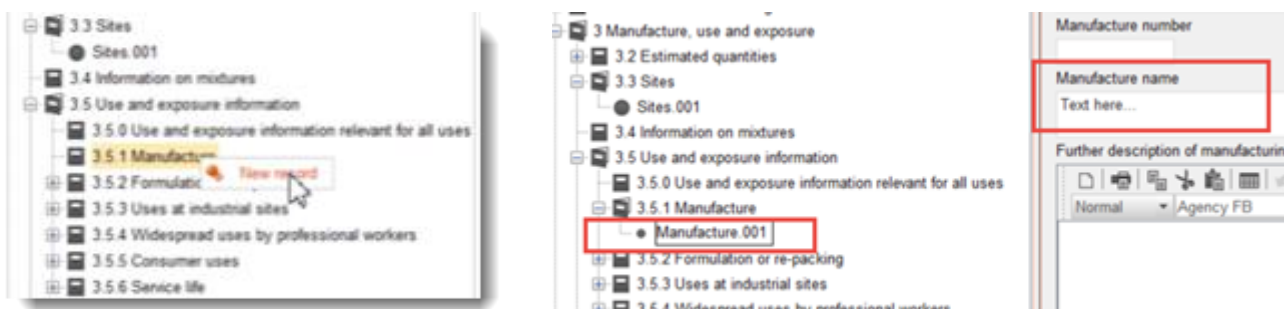
STEP 3: … ERC and PROC

STEP 4: Go to section 3.3 Sites. Link the manufacture use to the site

3.5. Failure TCC_06_01

| TCC_06_01 | 6 | Ecotoxicologic al information, Sediment (freshwater) | Ecotoxicologic al Information-co py | Section 6 is not complete. An endpoint summary must be created under 'Ecotoxicological information', and each created summary must be complete. For each of the hazards, a selection must be made in the 'Hazard assessment conclusion' picklist. If 'PNEC' was selected, the value and unit must be provided in the fields under the conclusion. | Completeness check | ❌ Failure |

3.5.1. How to correct?

STEP 1: Identify the reason for the error > Hazard assessment conclusion not filled in

3.6. Failure TCC_07_01

| TCC_07_01 | 7 | Toxicological information, GP-INH-SYS-L T | Toxicological information | Section 7 is not complete. An endpoint summary must be created under 'Toxicological information', and each created summary must be complete. For each of the hazards for 'Workers' and 'General population' a selection must be made in the 'Hazard assessment conclusion' picklist. If 'DNEL', 'DMEL' or 'other toxicological threshold' was selected, the value and unit must be provided in the fields under the conclusion. | Completeness check | ❌ Failure |
| TCC_07_01 | 7 | Toxicological information, W-EYE-LOC | Toxicological information | Section 7 is not complete. An endpoint summary must be created under 'Toxicological information', and each created summary must be complete. For each of the hazards for 'Workers' and 'General population' a selection must be made in the 'Hazard assessment conclusion' picklist. If 'DNEL', 'DMEL' or 'other toxicological threshold' was selected, the value and unit must be provided in the fields under the conclusion. | Completeness check | ❌ Failure |

3.6.1. How to correct?

STEP 1: Identify the exact location of the error

STEP 2: Identify the reason for the error > Hazard assessment conclusion not filled in

3.7. Failure TCC_11_01

3.7.1. How to correct?

STEP 1: Create a new record in section 11

STEP 2: Identify which fields have not been filled with the required information.