



# Ezerċizzju prattiku

Bi spjegazzjoni



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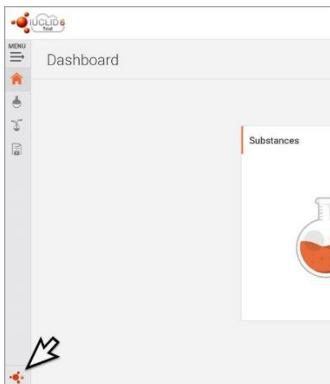
## 1. Introduzzjoni

Dan il-materjal ta' eżerċizzju għandu l-għan li jagħtik l-ewwel kuntatt b'IUCLID 6 u l-Assistent ta' validazzjoni qabel tibni d-dossier ta' reġistrazzjoni tiegħek ghall-iskadenza ta' reġistrazzjoni ta' REACH 2018. Huwa rrakkommandat li l-ewwel taqra l-preżentazzjoni (madwar siegħa) imbagħad tkompli bl-eżerċizzju (madwar siegħa). L-istruzzjonijiet tal-eżerċizzju huma segwiti mill-ispjegazzjoni. L-ispjegazzjoni tipprovdilek parir tekniku dwar kif tagħmel l-eżerċizzju; ma tipprovdix parir regolatorju. Innata li s-sett tad-data ta' sustanza ta' taħriġ ma jinkludix data reali u m'għandux jittieħed bħala mudell biex jiġu ssodisfati r-rekwiziti ta' REACH.

Għall-eżerċizzju sejkollok bżonn IUCLID 6. Tista' tmur fuq is-sit web ta' IUCLID 6, tirreġistra/tillogga u tniżżeġ il-verżjoni kompjuterizzata ta' IUCLID 6. Ara <https://iuclid6.echa.europa.eu/>.

Alternattivament, tista' tuża s-servizz ta' Prova tal-Cloud ta' IUCLID li huwa aċċessibbli permezz tas-sit web tal-ECHA fuq <https://echa.europa.eu/support/dossier-submission-tools/echa-cloud-services>.

Tista' tillogġja online bil-kredenzjali tal-kont tiegħek tal-ECHA (l-istess għall-kont tiegħek ta' REACH-IT) u tabbona għas-servizz ta' Prova tal-Cloud ta' IUCLID. Sabiex tipparteċipa f'dan l-eżerċizzju bl-użu tal-cloud ta' IUCLID, jekk jogħġibok ikklikk ja fuq l-ikona ta' IUCLID fin-naħha t'isfel tax-xellug tal-paġna dashboard tal-cloud ta' IUCLID. Dan se jniedi l-verżjoni tal-klient ta' IUCLID, jiġifieri kif jidher se jkun l-istess bħal IUCLID kompjuterizzat, u int se tkun tista' ssegwi r-ritratti tal-iskrin ta' din l-ispjegazzjoni tal-eżerċizzju.



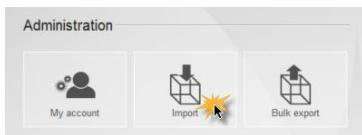
## 2. Istruzzjonijiet

### 2.1. Tifsira

Int ir-Reġistrant principali tal-ECHA\_Sustanzata TaħriġX. Ir-reġistrazzjoni konġunta tkopri l-medda ta' tunnellaġġ ta' 10-100 t/y. Barra minn hekk, it-tunnellaġġ manifatturat tiegħek stess ta' din is-sustanza huwa ta' 10-100 t/y. Bħala reġistrant principali, int tipprovd i-Gwida dwar Użu Sigur (GSU, Guidance on Safe Use fit-taqSIMA 11 ta' IUCLID) u r-Rapport dwar is-Sigurtà Kimika (CSR fit-taqSIMA 13 ta' IUCLID) għan-nom tal-membri tal-preżentazzjoni konġunta.

### 2.2. L-eżerċizzju pass wara pass

**PASS 1:** Niedi IUCLID 6 u importa l-fajl ta' sustanza ta' taħriġ (format .i6z).



## PASS 2:Sib is-sustanza tiegħek



## PASS 3:Haddem l-Assistent ta' validazzjoni fuq is-sett tad-data tas-sustanza tiegħek u kkoregi l-iżbalji tal-preżentazzjoni rrappurtati kollha

Chemical name Training Substance Z	Legal entity name Example Company 1
Test Substance X	European Chemicals Agency Open
<input type="button" value="Create Dossier..."/> <input type="button" value="Print..."/> <input type="button" value="Generate report..."/> <input type="button" value="Export..."/> <input type="button" value="Delete"/> <input style="background-color: #ff0000; color: white; font-weight: bold;" type="button" value="Validate"/>	

**Validation assistant wizard**

Validation assistant - Submission type specification

**Dossier type**

Select submission type: REACH Registration 10 - 100 tonnes

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

Provide the submission type information in order to determine the scenario of the validation.

[Back](#) [Next](#) [Finish](#) [Cancel](#)

**Validation assistant wizard**

Validation assistant - Enter additional information concerning your dossier

**Type of submission**

Joint submission

Chemical safety report

Guidance on safe use

**Tonnage band(s) of the lead registrant**

Tonnage band

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

Data sharing issues

Fee waiving (1-10 tonnes, not fulfilling Annex III criteria and voluntarily providing full Annex VII)

## PASS 4: Kun cert li ma jkun għad baqa' l-ebda nuqqas tal-preżentazzjoni. Ohloq id-dossier tiegħek. Imla l-informazzjoni tal-intestatura tad-dossier skont it-tifsira pprovduta fil-bidu tal-eżerċizzju.

Chemical name	Legal entity name	Reference
Training SubstanceZ	Example Company 1	Gold / 231
TestSubstanceX	<a href="#">Open</a> <a href="#">Create Dossier...</a>  <a href="#">Print...</a> <a href="#">Generate report...</a> <a href="#">Export...</a> <a href="#">Delete</a> <a href="#">Validate...</a> <a href="#">Agency</a>  ECH 1111	ECH

**PASS 5:** Haddem l-Assistent ta' validazzjoni fuq id-dossier finali tiegħek biex tivverifika li m'għad baqa' l-ebda nuqqas tal-preżentazzjoni.

- Jekk l-Assistent ta' validazzjoni xorta jibqa' juri l-iżbalji: mur lura għas-sett tad-data tas-sustanza tiegħek, ikkoreġi l-iżbalji mbagħad oħloq dossier ġdid.
- Jekk l-Assistent ta' validazzjoni ma jirrapporta l-ebda żball: esporta d-dossier tiegħek u ssejvjah fuq il-kompjuter tiegħek.

### **Id-dossier ta' taħriġ tiegħek issa lest!**

### 3. Spjegazzjoni għall-eżerċizzju

Is-soluzzjonijiet li ġejjin jipprovdu biss parir tekniku dwar kif tikkoreġi l-iżbalji tal-preżentazzjoni. L-ispjegazzjonijiet għala ġerta informazzjoni hija meħtieġa mhumiekk fil-kamp ta' applikazzjoni ta' dan il-materjal ta' taħbi iż-żgħid jistgħad. "Kif tipprepara reġistrazzjoni u dossiers tal-PPORD" fuq <https://echa.europa.eu/manuals>.

#### 3.1. Għajniet dwar kif tuża l-Assistent ta' validazzjoni

Wara li tikkoreġi nuqqas, ikklikkja fuq l-ikona "save" ("issejvja") f'IUCLID u tella' mill-ġdid ir-rapport tal-Assistent ta' validazzjoni billi tikklikkja fuq il-buttna re-check (ivverifika mill-ġdid) (li tidher fir-ritratt tal-iskrin hawn fuq). Jekk in-nuqqas ġie kkoreġut kif meħtieġ, allura l-messaġġ ta' nuqqas rispettiv telaq mir-rapport.

Xi drabi jista' jiġi li "titlef" l-Assistent ta' validazzjoni tiegħek. Meta tiprova terġa' tifħu tirċievi messaġġ ta' żball li jgħid li dan diġà miftuħ. Tista' "ssib" l-Assistent ta' validazzjoni billi tikklikkja fuq l-ikona tal-Assistent ta' validazzjoni fin-naħha t'isfel tal-lemin tal-paġna ta' IUCLID tiegħek.

## 3.2. Nuqqas BR176 u BR177

**Kumment:** Meta tikkoregi BR177, BR176 jiġi kkoreġut ukoll

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	
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	

### 3.2.1. Kif tikkoreġih?

**PASS 1:** F'dan l-eżerċizzju, int ir-registrant prinċipali u għalhekk teħtieg żewġ rekords ta' kompożizzjoni fit-taqṣima 1.2 ta' IUCLID: wieħed immarkat bħala "kompożizzjoni ta' entità legali tas-sustanza" u t-tieni wieħed immarkat bħala "kompożizzjoni konfinali tas-sustanza". It-tieni rekord ta' kompożizzjoni għandu jiddeskrivi l-konfini tar-reġistrazzjoni konġunta.

Dawn l-iżbalji ta' regoli tal-operazzjonijiet jindikaw li teħtieg tagħmel għażla fil-kaxxa "Type of composition" ("Tip ta' kompożizzjoni") fit-tieni rekord ta' kompożizzjoni u tagħżel "boundary composition of the substance" ("kompożizzjoni konfinali tas-sustanza").

The screenshot shows the REACH software interface. On the left is a navigation panel with sections like 'REACH Complete table of c...', 'Text filter', and a tree view of '1 General information', '1.2 Composition', and 'Composition'. The main window shows 'CORE / Composition / Composition / ECHA\_TrainingSubstance\_'. Under 'General Information', it shows 'Name: Standard composition', 'Type of composition: boundary composition of the substance' (which is highlighted with a red box), 'State / form: solid: bulk', and 'Description of composition'.

## 3.3. Nuqqas 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	
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There is something wrong or missing in the second row of the table 'Analytical determination'

'Analytical determination'

### 3.3.1. Kif tikkoreğih?

**PASS 1:** Aghżel ir-ringiela 2 tat-tabella “Analytical determination” (“Determinazzjoni analitika”) u agħżel Edit (Editja)

The screenshot shows the 'Analytical information' section of the REACH Registration software. On the left, there's a tree view of registration details. The main area shows a table titled 'Methods and results of analysis'. One row in the table is selected, and its edit button ('Edit...') is highlighted with a red box.

**PASS 2:** Aghmel għażla mil-lista li tinżel “Analysis type” (“Tip ta’ analizi”)

This is a detailed screenshot of the 'Analytical determination' dialog box. It contains fields for 'Purpose of analysis' (set to 'Identification and/or quantification'), 'Analysis type' (highlighted with a red box), 'Type of information provided' (set to 'results'), 'Attached methods/results' (a file named 'Analytical results doc / 23.5 KB / application/msword'), 'Rationale for no results' (set to 'not relevant'), 'Justification' (empty), and 'Remarks' (empty). At the bottom are 'OK' and 'Cancel' buttons.

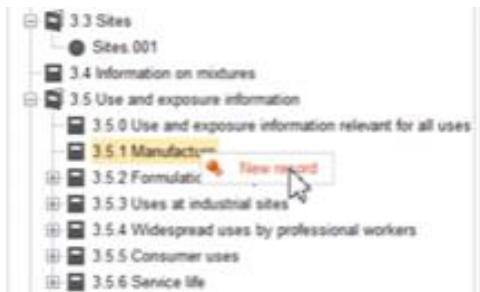
## 3.4. Nuqqas BR049 u TCC\_0303\_01

**Kumment:** Meta tikkoreġi BR049, TCC\_0303\_01 jiġi kkoreġut ukoll u viċe versa

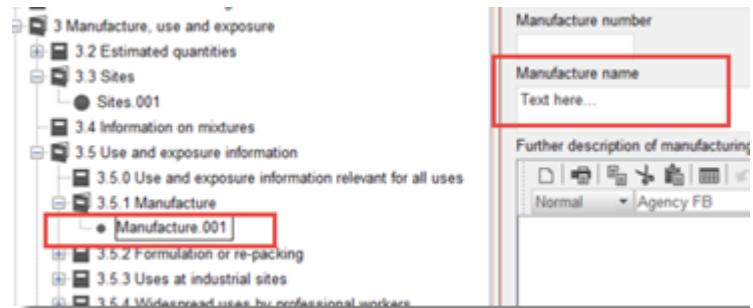
TCC_0303_01	3.3	Sites	Sites.001	If you indicated in section 1.1 that your 'Role in the supply chain' is 'Manufacturer', then you must provide at least one production site in section 3.3. To this end, you must create a record in section 3.3 and link a 'Site' to it. The contact address of each site must 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	<span style="color: red;">✗ Failure</span>
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	<span style="color: red;">✗ Failure</span>

### 3.4.1. Kif tikkoreğih?

**PASS 1:** Ohloq rekord gdid fit-taqSIMA 3.5.1



**PASS 2:** Bħala minimu imla l-oqsma Manufacture name and ... (Isem tal-manifattura u ...)



**PASS 3:** ... ERC and PROC (... ERC u PROC)

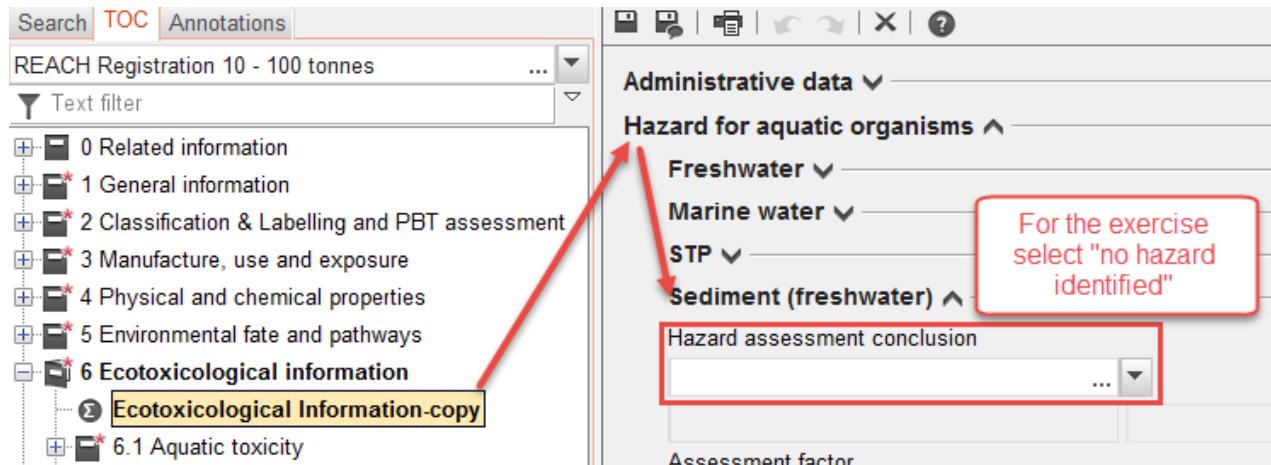
**PASS 4:** Mur fit-taqSIMA 3.3 Siti. Illinkja l-użu tal-manifattura mas-sit

### 3.5. Nuqqas TCC\_06\_01

TCC_06_01	6	Ecotoxicological information, Sediment (freshwater)	Ecotoxicological Information-copy	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
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#### 3.5.1. Kif tikkoreġiħ?

**PASS 1:** Identifika r-raġuni għall-iżball > Hazard assessment conclusion not filled in (Konklużjoni tal-istima tal-periklu mhijiex mimilja)



The screenshot shows the REACH Registration interface. On the left, the Table of Contents (TOC) lists various sections, with 'Ecotoxicological Information-copy' highlighted. On the right, the 'Hazard for aquatic organisms' section is open, showing options for Freshwater, Marine water, STP, and Sediment (freshwater). A red arrow points from the TOC to the 'Hazard assessment conclusion' dropdown. A red box surrounds this dropdown with the text: 'For the exercise select "no hazard identified"'.

### 3.6. Nuqqas TCC\_07\_01

TCC_07_01	7	Toxicological information, GP-INH-SYS-LT	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. Kif tikkoreġih?

**PASS 1:** Identifika fejn jinsab eżatt l-iżball

Rule ^	Section nu...	Section name	Document n...	Message
TCC_07_01	7	Toxicological information	GP-INH-SYS-LT	<p>GP - General Population  INH - Hazard via <b>inhalation route</b>  SYS - <b>Systemic effects</b>  LT - Long term exposure</p> <p>The conclusion.</p> <p>Summary must be created created summary must be workers' and 'General hazard assessment other toxicological threshold' provided in the fields under the conclusion.</p>
TCC_07_01	7	Toxicological information	W-EYE-LOC	<p>Section 7 is not complete. An endpoint summary must be created created summary must be workers' and 'General hazard assessment other toxicological threshold' provided in the fields under the conclusion.</p> <p>W - Workers  EYE - Hazard for the <b>eyes</b>  LOC - Local effects</p>

**PASS 2:** Identifika r-raġuni għall-iżball > Hazard assessment conclusion not filled in (Konklużjoni tal-istima tal-periklu mhijiex mimlija)

REACH Registration 10 - 100 tonne: ...

Text filter

- + 0 Related information
- + \* 1 General information
- + 2 Classification & Labelling and PBT
- + \* 3 Manufacture, use and exposure
- + \* 4 Physical and chemical properties
- + \* 5 Environmental fate and pathways
- + \* 6 Ecotoxicological information
- + \* 7 Toxicological information
  - Σ Toxicological information
  - + 7.1 Toxicokinetics, metabolism a

**Administrative data**

Workers - Hazard via inhalation route

Workers - Hazard via dermal route

Workers - Hazard for the eyes

Additional information - workers

General Population - Hazard via inhalation route

Systemic effects

Long term exposure

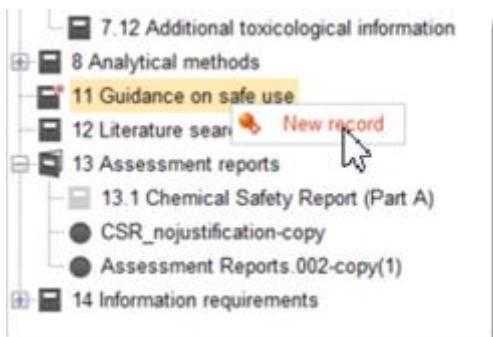
Hazard assessment conclusion

### 3.7. Nuqqas TCC\_11\_01

TCC_11_03	11	Guidance on safe use		Section 11 is incomplete. At the selected tonnage band, at least one record must be created in section 11. Each record must contain at least the following information related to the guidance on safe use: - First-aid measures - Fire-fighting measures - Accidental release measures - Handling and storage	Completeness check	Failure
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### 3.7.1. Kif tikkoreġih?

**PASS 1:** Ohloq rekord ġdid fit-taqSIMA 11



## PASS 2: Identifika liema kaxex ma mtlewx bl-informazzjoni meħtieġa.

The screenshot shows the software interface with red arrows indicating the mapping between the navigation tree and the content area:

- Navigation tree (left):**
  - 7.12 Additional toxicological information
  - 8 Analytical methods
  - 11 Guidance on safe use** (highlighted)
  - 12 Literature search
  - 13 Assessment reports
  - 14 Information requirements
- Content area (right):**
  - First-aid measures**
  - Fire-fighting measures**
  - Accidental release measures**
  - Handling and storage**
  - Transport information**
  - Exposure controls / personal protection**
  - Stability and reactivity**
  - Disposal considerations**

The 'New record' button is located at the top of the content area, just below the navigation tree.