

## Stakeholders' Day 30 January 2018

### IUCLID Cloud exercise

#### Outline

1. Legend – who are you?
2. Join a joint submission in REACH-IT
3. Prepare your member dossier in IUCLID Cloud
  - Fill the mandatory information requirements (after this point you may go straight to the dossier creation and submission)
  - Add additional/optional information (if you feel strong and time permits, i.e., extra tasks for advanced users)
4. Create your dossier
5. Submit your dossier to REACH-IT

#### 1. Legend

You are REACH manager in a medium-sized company in an EU country. Your company is **manufacturing** the substance **2-methoxy-1-methylethyl acetate** at **10-100 tonnes/year**. This substance has been pre-registered in 2008 and now you are about to create and submit the registration dossier for it. You have had successful negotiations within the SIEF and will join the joint submission (JS) as a **member**. However, you have some data which you wish to submit outside the joint dossier.

You have decided to create your dossier using IUCLID Cloud. You found that to be the best option for you because it is easily accessible over the internet, it is always up-to-date, there is no need to worry about the backup files and it does not require any IT skills to be able to prepare the dossier. Since you will be opting out some data, you could not have used the REACH-IT online member creation tool.

#### 2. Join a joint submission in REACH-IT

**STEP 1:** Open the REACH-IT Training environment and log-in with the username and password you have been provided: <https://edu-reach-it.echa.europa.eu/reach/>

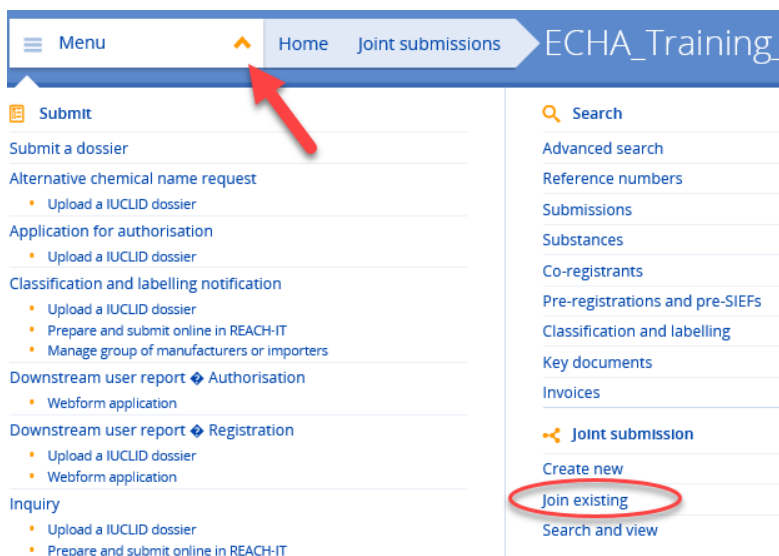
In REACH-IT, at any point you need help, click on the integrated help button in the upper right corner.



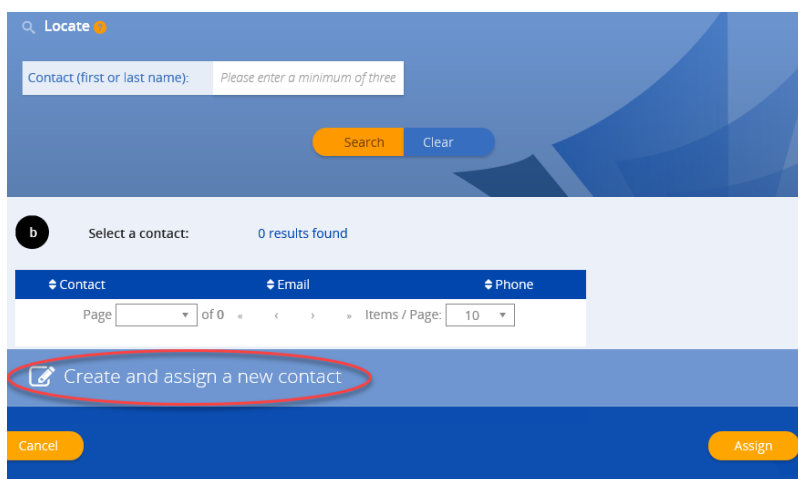
**STEP 2:** Join the joint submission using the JS name and the token combination.

JS name: **SHD\_IT\_tools\_training**

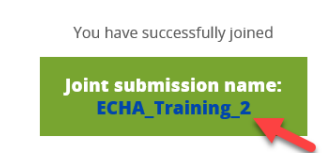
Token: **b04-0a9-64ca-1553138095**



**STEP 3:** Assign a contact person to the joint submission. If there is no contact already created, you can create one.



**STEP 4:** Fill the required information and confirm your membership. Click on the joint submission name on the confirmation page to see the details.

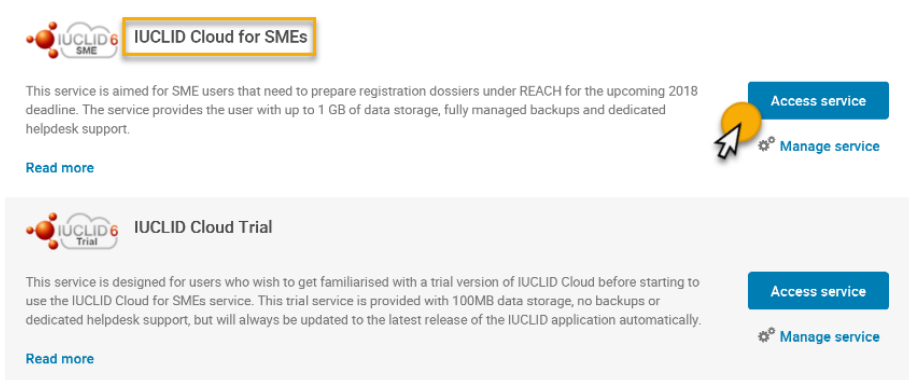


You have now joined the joint submission.

### 3. Create your member dossier in IUCLID Cloud

**STEP 1:** Open IUCLID Cloud training environment by signing in at the following link:  
<https://ecs-ga.echa.europa.local/cloud/subscriptions>

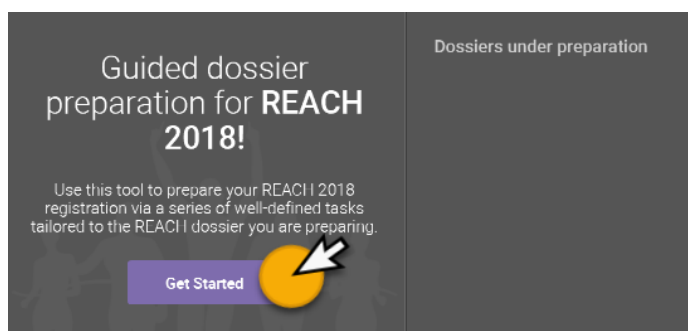
**STEP 2:** Enter IUCLID Cloud for SMEs



The screenshot shows two subscription options for IUCLID Cloud. The first is 'IUCLID Cloud for SMEs', which is highlighted with a yellow box. It includes a description: 'This service is aimed for SME users that need to prepare registration dossiers under REACH for the upcoming 2018 deadline. The service provides the user with up to 1 GB of data storage, fully managed backups and dedicated helpdesk support.' Below the description are 'Read more', 'Access service', and 'Manage service' buttons. The second option is 'IUCLID Cloud Trial', with a description: 'This service is designed for users who wish to get familiarised with a trial version of IUCLID Cloud before starting to use the IUCLID Cloud for SMEs service. This trial service is provided with 100MB data storage, no backups or dedicated helpdesk support, but will always be updated to the latest release of the IUCLID application automatically.' It also has 'Read more', 'Access service', and 'Manage service' buttons.

**STEP 3:** Start preparing your dossier. You will be guided through your dossier preparation via series of tasks.

You are given all the information you need in the correct order. If you are missing some information in this script, e.g. public name, third party, trade name, other identifiers, etc., then you may consider that this information is only **optional** in the dossier and the related fields may be left empty in this exercise, and you may click '**Next**' to move on. Click '**Finish**' to save and exit the section.



The screenshot shows a dark grey interface for 'Guided dossier preparation for REACH 2018!'. It includes the text: 'Use this tool to prepare your REACH 2018 registration via a series of well-defined tasks tailored to the REACH dossier you are preparing.' Below this is a purple 'Get Started' button with a yellow arrow pointing to it. To the right, there is a section titled 'Dossiers under preparation'.

**STEP 4:** Indicate the substance and registrant type & tonnage band

- Create a new substance: **SHD2018 substance**
- Type of registrant: **member**
- Tonnage band: standard **10-100** tonnes/year.

**STEP 5:** Provide your dossier information starting with the mandatory information for any member dossier. After the mandatory information, you have the opportunity to add some additional/optional information that is not provided by lead on behalf of all JS (CSR, GSU), or which you wish to opt-out (e.g. GHS):

The screenshot shows a web interface for REACH registration. It is divided into two main sections: 'Mandatory information' and 'Optional information'. The 'Mandatory information' section includes 'Substance identification' and 'Use and exposure information'. The 'Optional information' section includes 'Chemical safety report and Guidance on safe use', 'Annex III criteria', and 'Opt-out information for REACH registration'. Each item is represented by a clipboard icon.

### STEP 6: Substance identification

This screenshot shows the 'Substance identification' section of the REACH registration form expanded. A yellow dashed arrow points from the 'Substance identification' item in the main list to a detailed view of this section. The detailed view includes three sub-sections: 'Identification' (dated 26/01/2018 19:32), 'Composition', and 'Analytical Information'. Each sub-section is represented by a clipboard icon.

- Substance name: **2-methoxy-1-methylethyl acetate**
- Reference substance: create a new reference substance
  - Name **2-methoxy-1-methylethyl acetate**
  - Inventory number: **203-603-9**
  - IUPAC name: **1-Methoxypropylacetat-2**
  - CAS number: **108-65-6**
  - Molecular formula: **C<sub>6</sub>H<sub>12</sub>O<sub>3</sub>**
  - Molecular weight: ca **132.16**
  - Structural formula: upload the attachment from the IUCLID6 website



- Type of substance: **monoconstituent**
- Origin: **organic**
- Role in the supply chain: **manufacturer**

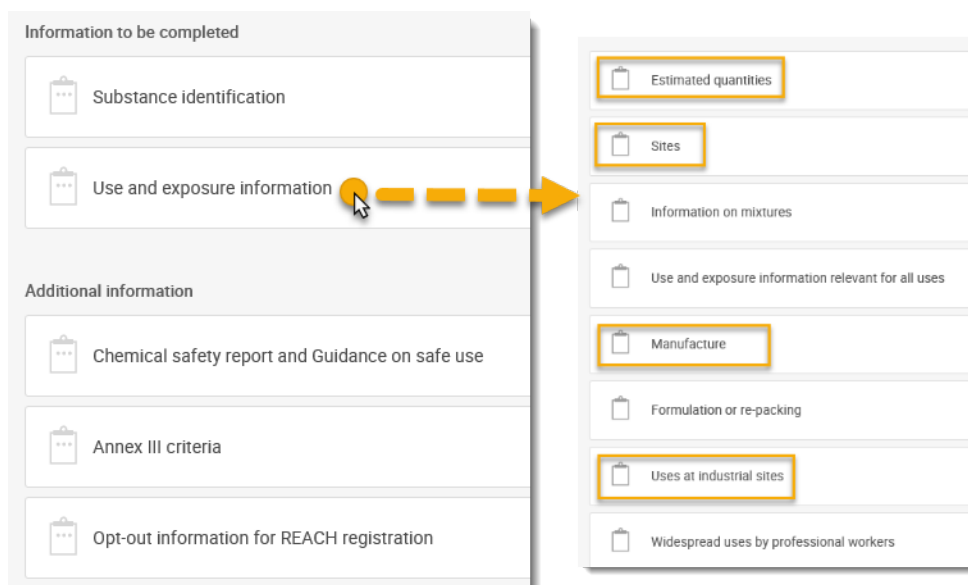
### STEP 7: Information on composition

- Name: **Legal entity composition**
- Type of composition: **legal entity composition** of the substance
- State/form: **liquid**
- Degree of purity: **98-100% (w/w)**
- Constituents: add a new item
  - Reference substance: Since the registered substance is a monoconstituent, the main constituent is the **same substance** as the registered substance with the **typical concentration** of ca **100% (w/w)**.

### STEP 8: Analytical information

- Analytical determination: You have **identified** and **quantified** your substance with the help of a **gas chromatography (GC)**. In both cases, you will provide the **results** of your test by attaching the file that can be downloaded from the IUCLID6 website ('Analytical results for training').

### STEP 9: Use and exposure information


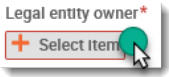


#### STEP 9a: Estimated quantities

It is advisable to provide the estimated quantities of all the available years, but at least the information of the last three years should be provided for phase-in substances.

- Year 2015: 15 tonnes manufactured
- Year 2016: 17 tonnes manufactured
- Year 2017: 20 tonnes manufactured

### STEP 9b: Sites

- Create a new site 
  - Site name: insert a name
  - Legal entity owner: link a legal entity by clicking on 'Select item' 
  - Contact address: add the contacts (postal address, phone, e-mail)
- Manufacture /own use: can be linked only after the manufacture use is filled (i.e. after the next section on Uses is filled)

### STEP 9c: Manufacture

You are a manufacturer of the substance, therefore, you need to fill the **Manufacture** section.

At least one contributing activity/technique for the environment and one contributing activity/technique for workers must be provided. Each contributing activity must be described with the appropriate 'Environmental release category' and 'Process category' codes, or an 'other:' category must be filled in.

- Registration/ Notification status for the use: make a relevant selection
- Manufacture name: **add a name**
- Contributing activity/technique for the environment: **add new item**
  - Name of activity/technique: Manufacture in contained system, no water involved
  - Environmental release category (ERC): **ERC1**
- Contributing activity/technique for workers: **add new item**
  - Name of activity/technique: **Closed manufacturing process**
  - Process category (PROC): **PROC1**

### STEP 9d: Sites

Now go back to **Sites** and link this manufacture use to your **Manufacture /own use**

### STEP 9e: Uses at industrial sites

Additionally, at least one use **other than manufacture** should be provided or a justification for no uses should be specified. In this case, you will be filling the field of the **uses at industrial site**.

For this, the fields 'Technical function of the substance during use' and 'Subsequent service life relevant to this use' must be filled in. In addition, at least one contributing activity/technique for the environment and one contributing activity/ technique for workers must be provided. Each contributing activity must be described with the appropriate 'Environmental release category' and 'Process category' codes, or an 'other:' category must be filled in.

- Registration/ Notification status for the use: **make a relevant selection**
- Use name: **Use of vehicle cleaning product**
- Further description of use: Spraying and rinsing of cleaning product at car manufacturing lines (largely automated process – mainly open – ambient temperature)
- Contributing activity/technique for the environment: **add new item**
  - Name of activity/technique: Automated water based washing of large articles – Indoor use
  - Environmental release category (ERC): **ERC4**
- Contributing activity/technique for workers: **add new item**
  - Name of activity/technique: Transfer of products with manual coupling/decoupling
  - Process category (PROC): **PROC8b**
- Product category used: **PC35**
- Sector of end use: **SU17**
- Technical function of the substance during use: **Surfactant**
- Subsequent service life relevant for this use: **No**

#### STEP 10: Validate your data



You can validate the completeness and the quality of your data at any point during the dossier preparation by selecting 'Validate'. The Validation report will tell you what data is still missing and where. **Fix all the errors!** The aim is not to have any failing submission checks left.

- Dossier name: **name your dossier**
- Information provided by the lead on behalf of the members: **tick for both** (CSR and GSU)
- Phase-in status: **phase-in**

17 submission checks failed and need to be corrected before dossier creation

Once the failure is corrected, click to refresh the report

Validation assistant report

Submission checks 17 Quality checks 5

Composition.001  
Composition

Failure was found in the Composition (click on it to be taken to the error location). Read the message below to know how to correct it.

For each legal entity composition, at least one value and a unit must be provided for the 'Degree of purity'.

Re-validate

Any failure in the Validation assistant 'Submission checks' tab that is left uncorrected will lead to the technical completeness check (TCC) failure performed by the Agency. However, the TCC performed by ECHA staff will include some additional verifications which cannot

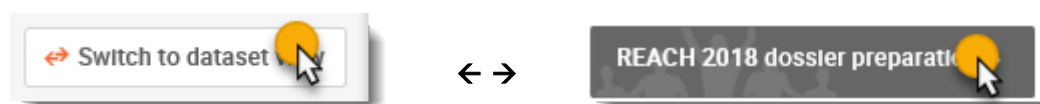
be replicated using the Validation assistant. Information on the areas of these additional verifications can be found in 22 languages at <https://echa.europa.eu/manuals>.

**STEP 11:** This is the **breakpoint** where you can decide whether you feel strong enough and whether there is time left, to continue with some additional tasks **STEP 12** to **STEP 18** (creating a C&L document, opting out a study, adding a PBT summary, own GSU and own CSR).

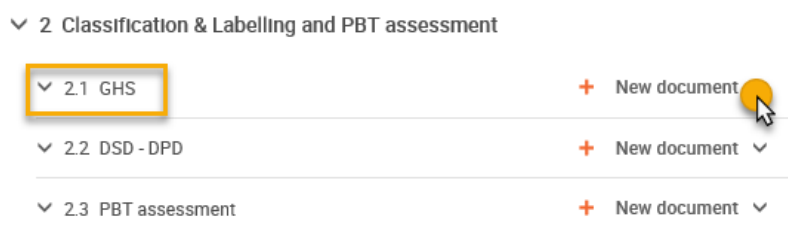
However, if you are happy with what you have learned about IUCLID Cloud so far, you may continue straight to **4. Create your dossier**.

## STEP 12: Classification & Labelling

In order to add information that is normally not required by member registrants but need to be added in some situations, you will need to switch your view to the **dataset mode**. Click at the button in the upper right corner. You can later switch back to the guided dossier preparation mode by clicking on the black button 'REACH 2018 dossier preparation'.



- Section 2.1 GHS: **add a new document**



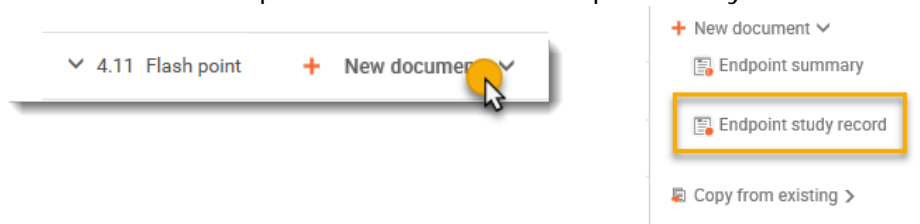
- Type of classification: **self-classification**
- Related composition: select and link your composition
- **Flammable liquids:**
  - Hazard category **Flam. Liquid 3**.
  - Hazard statement: **H226**: Flammable liquid and vapour.
- Specific target organ toxicity – single: **add new item**
  - Hazard category: **STOT Single Exp. 3**.
  - Hazard statement: **H336**: May cause drowsiness or dizziness.
  - Affected organs: **Central nervous system**
  - Route of exposure: **Oral**
- Specific target organ toxicity – repeated: **add new item**
  - Hazard category: **STOT Rep. Exp. 2**
  - Hazard statement: **H372**: Causes damage to organs or state all organs affected.



- Affected organs: **Central nervous system**
- Route of exposure: **Oral**
- Labelling signal word: **warning**
- Hazard pictogram: **GHS02: Flame**
- Hazard statements: **H204**: Fire or projection hazard.

### STEP 13: Flash point

You want to opt-out the joint information by adding your own flash point study. Go to section 4.11 Flash point and add a new endpoint study record.



- Endpoint: **flash point of flammable liquids**
- Type of information: **experimental study**
- Adequacy of study: **key study**
- Reliability: **1 (reliable without restriction)**
- Rationale for reliability: **guideline study**
- Reference: create new
  - Reference type: **publication**
  - Title: **Chemistry**
  - Author: **J.Agric**
  - Year: **2000**
  - Bibliographic source: **J. Agric. Chem. 38**
- Data access: **data published**
- Test guideline: **add new item**
  - Guideline: select one
- Type of method: select one
- Test material: select existing or create a new one
- Results and discussion / Flash point: enter a key result, 45.5 °C @ 101.3 kPa

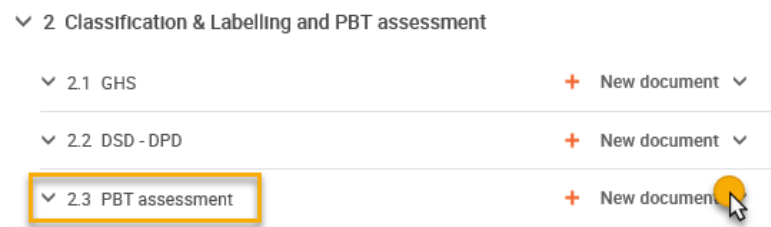
### STEP 14: Opt-out

In order to include the GHS information and the 'Flash point' document in your member dossier, you will need to include it for opt-out.

Still being in the dataset view, go to section **14 Information requirements**. Add a new document to opt-out information for REACH registration. Follow the wizard and **select** both the **GHS** and **'Flash point' documents** for opt-out. Add a **justification**.

## STEP 15: PBT assessment

Normally the PBT assessment is submitted by the lead registrant on behalf of the members. However, if the Chemical safety report is not submitted by the lead on behalf of members of the joint submission then each member should submit the PBT assessment.



- Section 2.3 PBT assessment: Create an endpoint summary document
- Assessed composition(s): **make the selection**
- 'PBT status': **substance is not PBT / vPvB**
- Justification: This substance is not classified as carcinogenic (category 1A or 1B), germ cell mutagenic (category 1A or 1B), or toxic for reproduction (category 1A, 1B or 2) and there is no evidence of chronic toxicity. Therefore, this substance is not PBT.

## STEP 16: Guidance on safe use

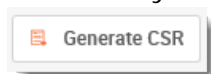
In the selected tonnage band, at least one record must be created in section Guidance on safe use. This information can be provided by the lead registrant on behalf of the whole JS but you are providing your own GSU. Therefore, as a minimum, you are expected to fill the following information:

- **First-aid measures:** Flush eyes thoroughly with water for several minutes.
- **Fire-fighting measures:** Keep people away. Isolate fire and deny unnecessary entry.
- **Accidental release measures:** Absorb with materials such as: Sand. Vermiculite. Collect in suitable and properly labelled containers.
- **Handling and storage:** Wash thoroughly after handling. Keep away from heat, sparks and flame.

## STEP 17: Chemical Safety Report (CSR)

A Chemical safety report (CSR) must be provided, or a justification for why a CSR is not required must be included the justification must fall under the reasons listed in Article 14(2) of REACH.).

**STEP 17b:** In the dataset view you are able to use the **CSR generator** available in the upper right corner.



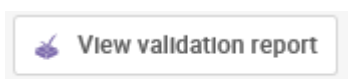
**STEP 17c:** Click on that button and generate CSR. Save it to your desktop.

**STEP 17d:** In your IUCLID section tree section 13 add a new document under 13.1 Chemical Safety Report (CSR)

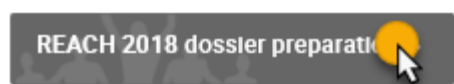
**STEP 17e:** Make the necessary selections in the pick-lists and upload your CSR file from desktop.

### STEP 18: Validate your data again

View the Validation assistant report to make sure that the information you have added is complete. Correct any submission failures reported.

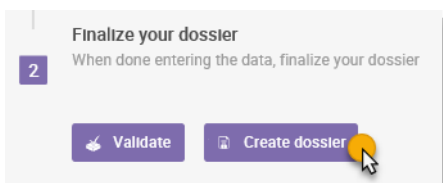


After that switch back to the guided dossier preparation mode.



## 4. Create your dossier

**STEP 1:** Create dossier out of the dataset and review the dossier header information.

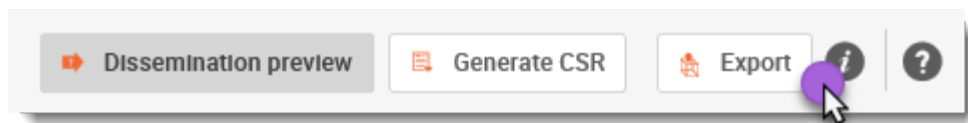


- If you **finished** the exercise at **STEP 10** it means that the lead provides Chemical safety report and Guidance on safe use on behalf of you and you should tick the respective tick-boxes.
- If you **continued** with the exercise and created your own CSR and GSU then you should not tick these tick-boxes.

Information provided by the lead on behalf of the member(s)

<input type="checkbox"/> Chemical safety report
<input type="checkbox"/> Guidance on safe use
<input type="checkbox"/> Review by an assessor

**STEP 2:** Open the created dossier and export it. save on your desktop. Your dossier is ready to be submitted to REACH-IT.

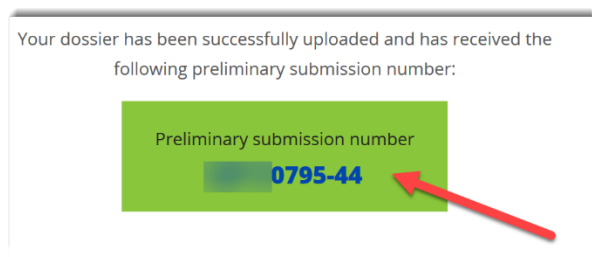


## 5. Submit your dossier to REACH-IT

**STEP 1:** Open the REACH-IT Training environment again and log-in with the username and password you have been provided: <https://edu-reach-it.echa.europa.eu/reach/>.

**STEP 2:** Submission to REACH-IT. You can submit the dossier to REACH-IT after the lead registrant has submitted and passed the business rules check.

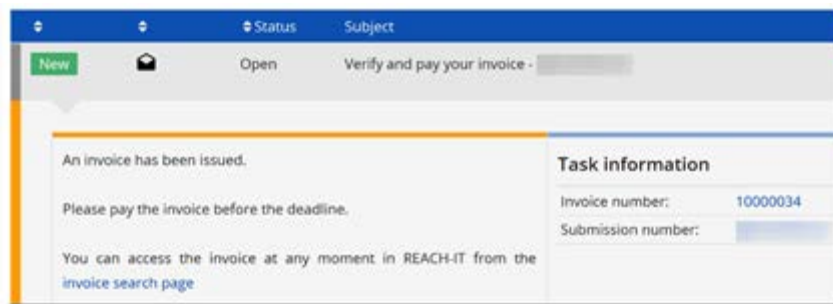
- Assign a contact person to your submission.
- Confirm the submission.
- Click on the preliminary submission number to see the submission page.



**STEP 3:** Follow up the progress of your dossier in REACH-IT:

- Check that your dossier passes business rules and technical completeness check.
- Find the invoice in your REACH-IT task box.
- When the submission is complete, find your registration decision on the submission page, under Key documents.

Submission processing steps		
1	✓	Pre-validation
2	✓	Business rules check
3	✓	Technical completeness check
4	⚙	Financial completeness check
5	⚙	Overall completeness check
6		Submission outcome



**Congratulations! Your substance is being successfully registered.**