

# Agenda

- Substance Identification – BR020, BR019, BR090
- Change of Tonnage Band – BR082
- Joint Submission – **BR027**, **BR063**, **BR091**
- Initial and Update Submission – **BR033**, **BR038**
- Legal Entity Inconsistency – **BR131**

# Joint Submission (JS) (BR027, BR063 & BR091)

The following type of submissions are possible:

- **Individual Submission**
- **Joint Submission**

REACH-IT Joint Submission Object (JSO)

Company role (lead, members) and UUID

Substance identifiers

Lead Registrant

Create the JSO in REACH-IT and distribute token

Member Registrant

Confirm their role in the JS via REACH-IT

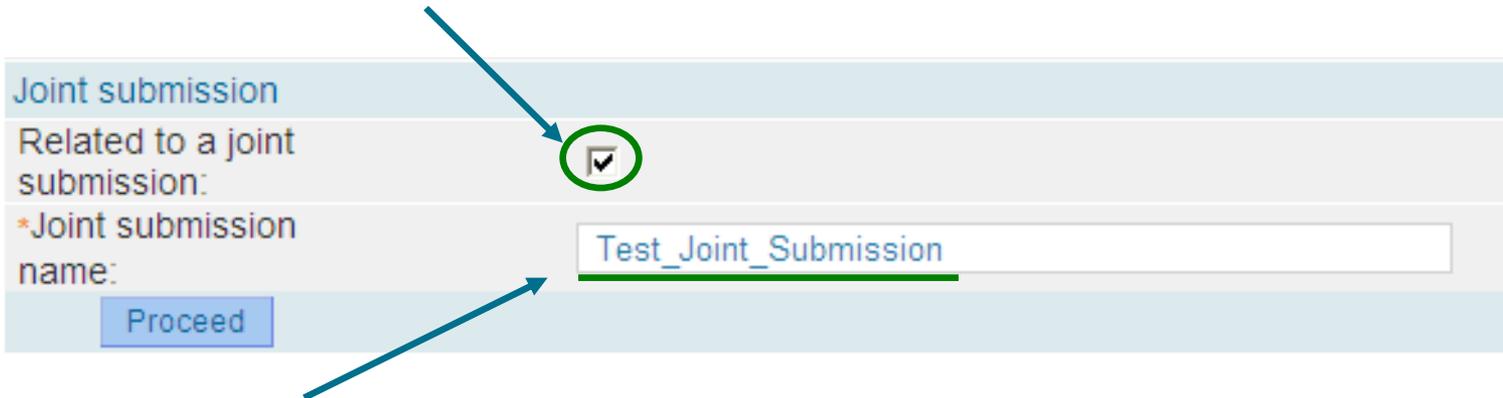
- BR027 is failing in the two following cases:
  - 1) **No JS is indicated in REACH-IT** submission page but the company is part of a JS for that substance.
  - 2) JS name is indicated in REACH-IT submission page but the **substance identity** (SID) provided in the dossier and in the JSO **does not match**.

1. **No JS is indicated in REACH-IT submission page but the company is part of a JS for that substance.**
  - REACH-IT allows you to consult your role in a JS. From the REACH-IT home page click on <Joint Submission> and on <view joint submission>.
  - This search option is available:

Home > View Joint Submissions

Pre-SIEF	
Registration / notification	
Joint submission	<b>Joint Submission criteria</b>
Classification and Labelling	Joint submission name: <input type="text"/>
My worklist	<b>Substance identity criteria</b>
Message box	Company name: <input type="text"/>
Inventories	Company UUID: <input type="text"/>
Legal entity change	EC number: <input type="text"/>
Process	CAS number: <input type="text"/>
	Chemical Name: <input type="text"/>
	<input type="button" value="Search"/> <input type="button" value="Clear"/>

- If your company is part of a JS for that substance, please ensure you select that you are part of a JS and you indicate the JS name during the submission in REACH-IT:



The screenshot shows a form section titled "Joint submission". It contains the following elements:

- A label "Related to a joint submission:" followed by a checked checkbox, which is circled in green. A green arrow points to this checkbox.
- A label "\*Joint submission name:" followed by a text input field containing the text "Test\_Joint\_Submission", which is underlined in green. A green arrow points to this input field.
- A blue "Proceed" button at the bottom left of the section.

- If you are part of a JS for the substance you aim to register but you do not indicate that in REACH-IT you will fail BR027.

2. JS name is indicated in REACH-IT submission page but **SID** provided in the dossier and in the JS object **does not match**.

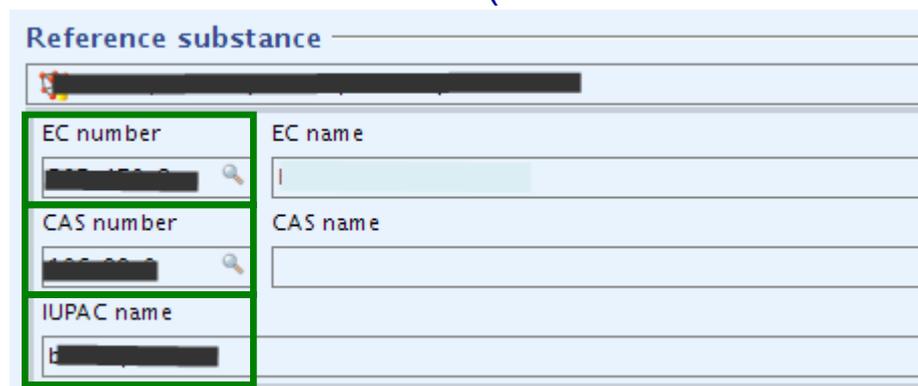
- You can see the SID information provided in the JSO by opening the “Joint Submission” section in REACH-IT entering the JS name:

*Substance identification*



EC Number	CAS Number	Name
[Redacted]	[Redacted]	[Redacted]

- Please ensure that these information are identical to the one indicated in IUCLID 5 section 1.1 (“Substance Identification”):



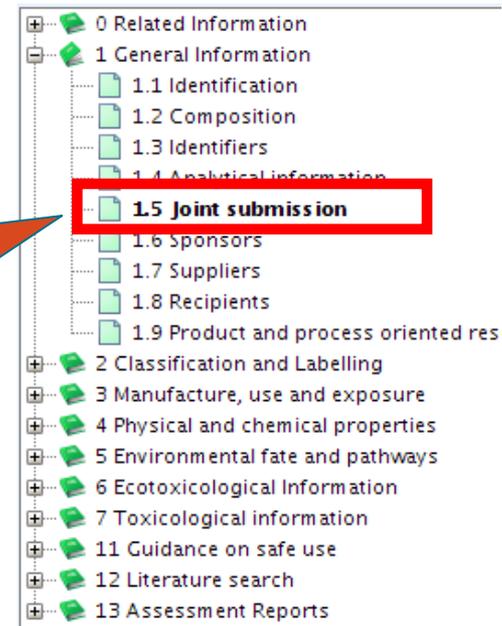
Reference substance	
[Redacted]	[Redacted]
EC number	EC name
[Redacted]	[Redacted]
CAS number	CAS name
[Redacted]	[Redacted]
IUPAC name	
[Redacted]	

# BR063



- BR063 checks that in case no JS is entered in REACH-IT submission page, IUCLID 5 section 1.5 is empty.

Dossier	
Dossier type:	Registration
Submission	
Submission Number:	00002955-27
Submission Date:	
Is the submission an update?	Yes
Is it a joint submission?	No



- You will fail BR063 when providing IUCLID section 1.5 with no JS in REACH-IT.

- Lead can provide some information on behalf of the members (e.g. chemical safety report and guidance on safe use)
- Members have to indicate in their dossier what the Lead provide on their behalf.

**Type of submission**

Joint submission

Data selected for opt-out

Document	Section	Justification...

[Go to link target](#)

---

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

Chemical safety report

Guidance on safe use

Review by an assessor

# BR091

- BR091 checks that what the member indicate in their dossier as provided by the lead (CSR and/or GSU) is matching with what is indicated in the Lead Dossier.

## MEMBER DOSSIER:

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

- Chemical safety report
- Guidance on safe use
- Review by an assessor

## LEAD DOSSIER:

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

- Chemical safety report
- Guidance on safe use
- Review by an assessor

- As members of a JS, please make sure that you have a clear communication with the lead and you are certain of what the lead is providing on behalf of the members and what not.

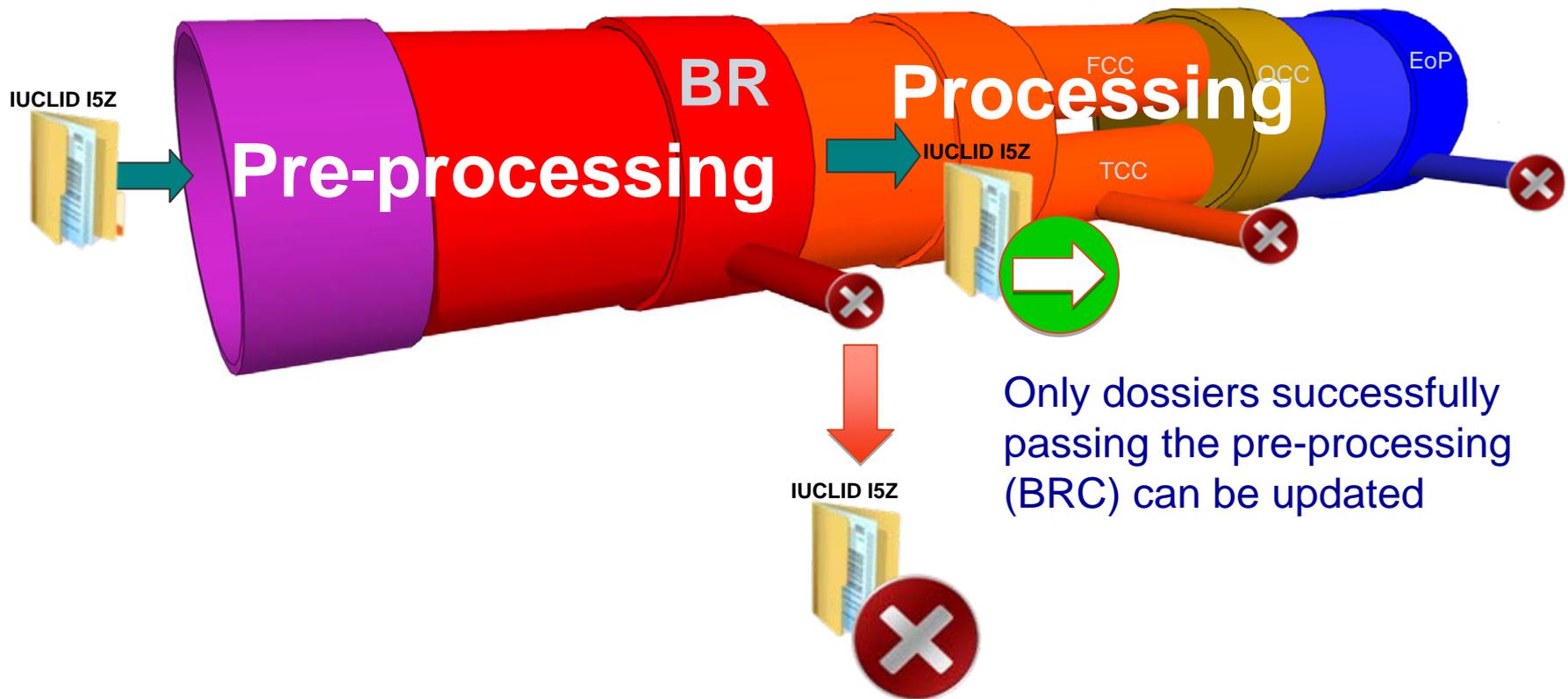
# Initial and Update Submission (BR033 & BR038)



- In order to correctly process your dossier it is critical that ECHA understands the submission context:
  - **initial submission**  
(e.g. first registration)
  - **update submission**
    - **Spontaneous Update**  
(e.g. change in the tonnage band)
    - **Requested Update**  
(e.g. re-submission after a 1<sup>st</sup> TCC failure)

# Initial and Update Submission (BR033 & BR038)

- When can you update a dossier?



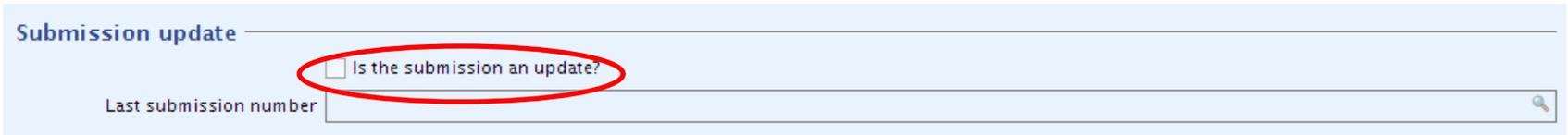
Any dossiers failing pre-processing can not be updated

# BR033

- **BR033** checks if the IUCLID5 dossier header is set correctly for **initial** or **update** submission.

## How to pass BR033?

- For **initial** submission the box '*is the submission an update?*' must not be ticked.



Submission update

Is the submission an update?

Last submission number

- For **update** submission the box '*is the submission an update?*' must be ticked and the last successful submission number must be provided.



Submission update

Is the submission an update?

Last submission number

- How to avoid BR033 failure?
  1. **If you failed BR you should re-submit a new dossier. Any reference to the previous dossier failing BR should not be made.**
  2. If you are submitting an update, please make sure that you include the submission number of the last successful submission\* in your dossier.
  3. If you are submitting an update, please make sure that the substance identity information is in line with the original registration/notification (i.e.an EC number is provided).

---

\*successful submission means a submission that passes BR. If you pass BR but fail TCC you are still requested to provide your previous submission number <sup>13</sup>

# BR038



- **BR038** checks that the dossier header is set correctly for spontaneous updates.
- **How to pass BR038?**
  1. If you are providing a spontaneous update please submit your dossier having ticked the fields '*Is the submission an update?*' and '*Spontaneous update*' as reason for updating in the dossier header.

Submission update

Is the submission an update?

Last submission number

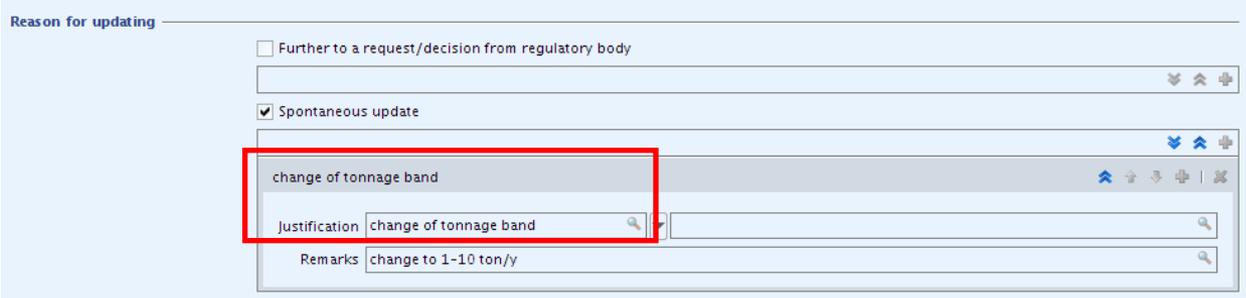
Reason for updating

Further to a request/decision from regulatory body

Spontaneous update

change of tonnage band

- Also, ensure that you select the appropriate update reason(s) (e.g. change in tonnage band).



Reason for updating

Further to a request/decision from regulatory body

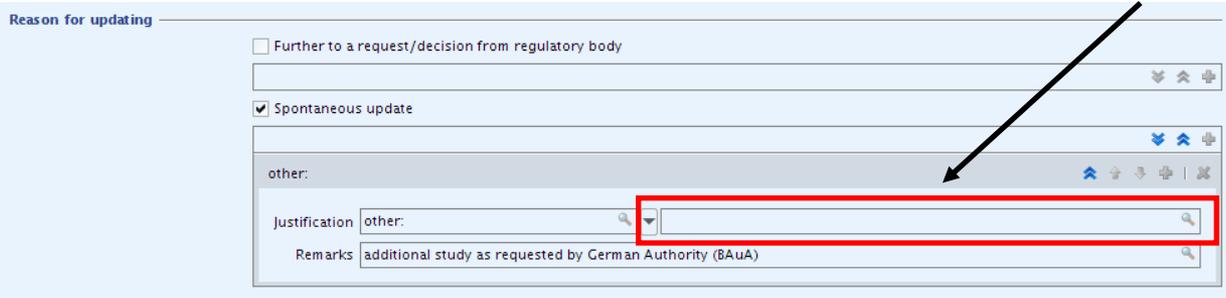
Spontaneous update

change of tonnage band

Justification change of tonnage band

Remarks change to 1-10 ton/y

- Multiple entry fields (multiple blocks) are allowed and can be used within the 'Spontaneous update' section.
- In case you selected the justification of type 'other:' please make sure that you provide a reason in the related field.



Reason for updating

Further to a request/decision from regulatory body

Spontaneous update

other:

Justification other:

Remarks additional study as requested by German Authority (BAuA)

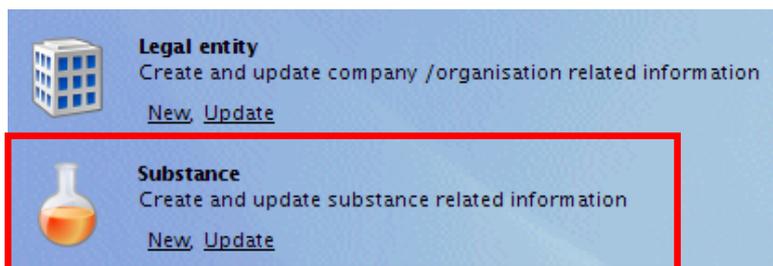
# Legal Entity inconsistency (BR131)

- Legal Entity (LE) are essential for ECHA to ensure that dossiers are properly handled and the regulatory process successfully carried out.
- In the process of creating a dataset, creating a dossier and submitting it, there are three instances where the legal entity needs to be indicated:
  1. IUCLID5 Section 1.1 (*'Substance Identification'*)
  2. IUCLID5 Dossier Header
  3. REACH-IT
- To avoid any ambiguity, you have to ensure that all these legal entities are the same.

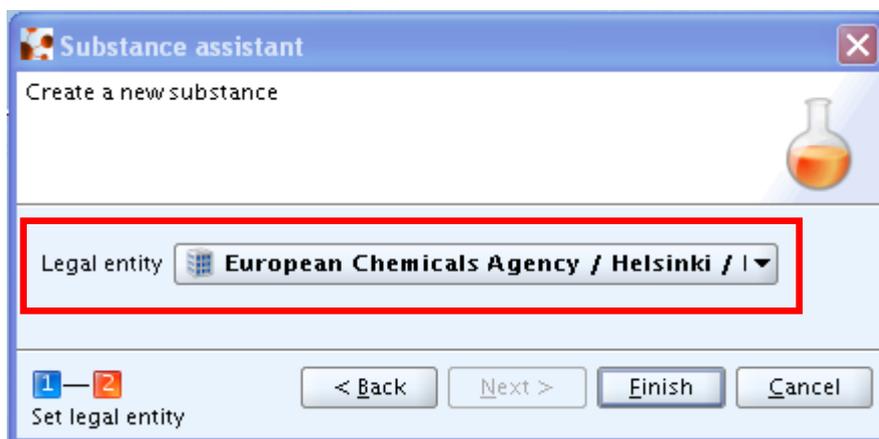
# 1. LE in IUCLID5 Section 1.1

- In IUCLID5 Section 1.1 (*Substance Identification*) the substance dataset is linked to a specific legal entity. How to create it?

1. Click on “*Substance*” in the IUCLID5 main screen.



2. Then enter the substance name (e.g. *Test\_Substance\_1*) and select the LEGAL ENTITY that will be associated to your substance dataset.



# 1. LE in IUCLID5 Section 1.1

3. You will be able to see the LE associated with your substance dataset in IUCLID5 Section 1.1 (*Substance Identification*).

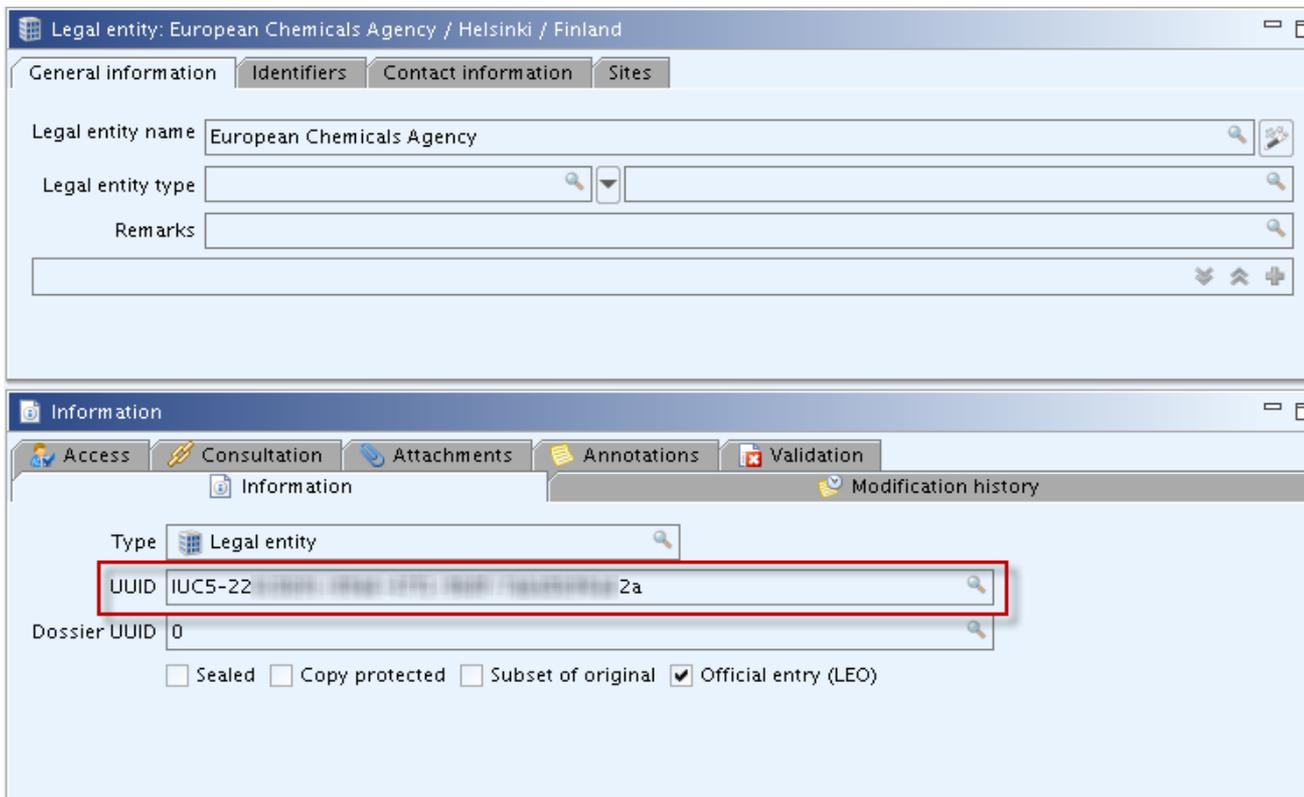


The screenshot shows the IUCLID5 interface for a substance dataset. The left sidebar displays a navigation tree with '1.1 Identification' selected. The main panel, titled 'Substance: Test\_Substance\_1 / European Chemicals Agency / Helsinki / Finland', shows the 'Substance identification' section. The 'Legal entity' field is highlighted with a red box and contains the text 'European Chemicals Agency / Helsinki / Finland'. A blue arrow icon on the right side of this field is circled in blue, with a red arrow pointing to it from below. Other fields include 'Chemical name' (Test\_Substance\_1), 'Public name', 'Legal entity flags', 'Third party flags', 'Third party', and 'Role in the supply chain' with 'Role flags' (Manufacturer, Importer, Only representative, Downstream user).

4. By Clicking on the blue arrow on the right end side of the “*Legal entity*” field you will be able to see the LE UUID associated with your substance dataset.

# 1. LE in IUCLID5 Section 1.1

5. In the “*Information*” field, under the “*Information*” tab, you can find the UUID of the legal entity associated with this substance.

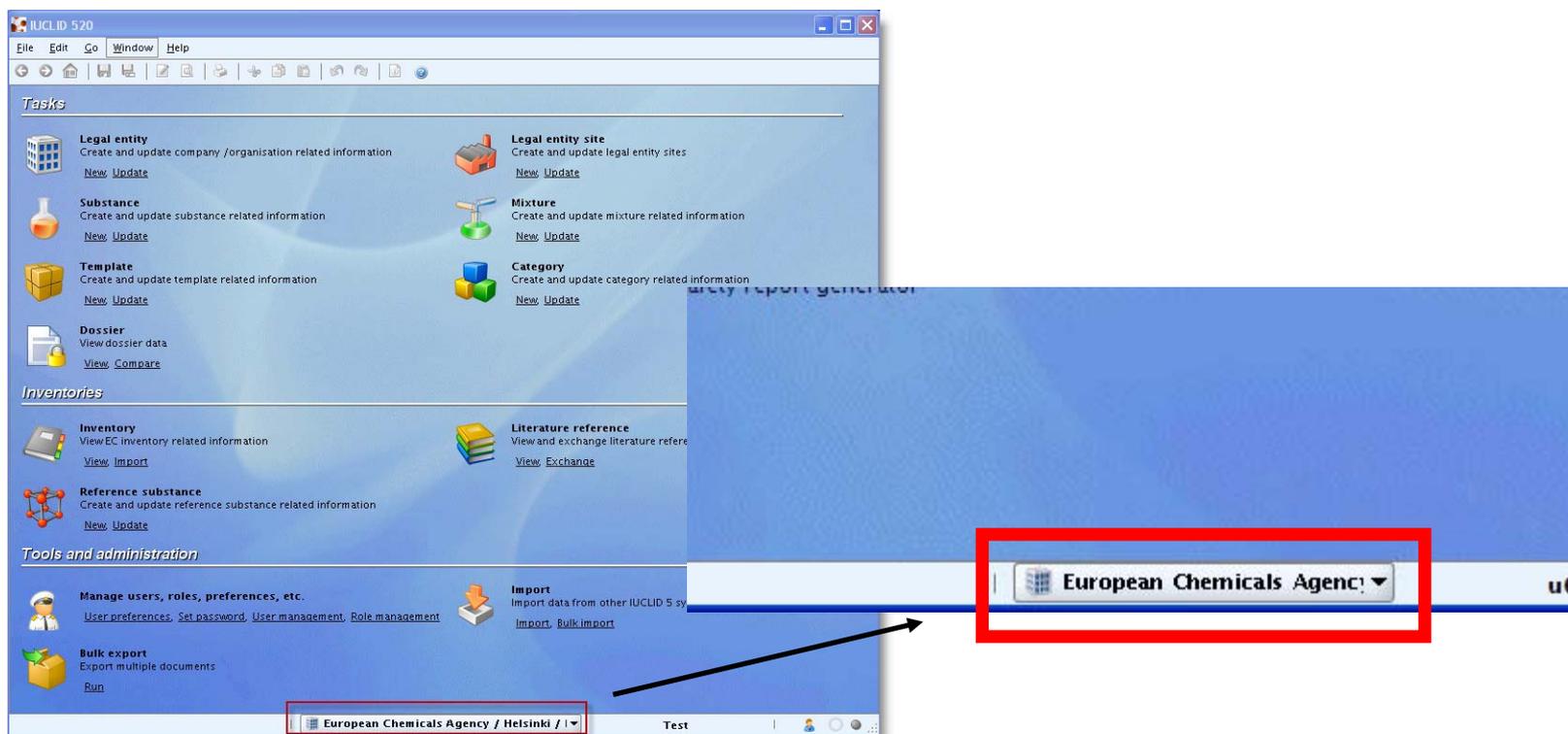


The screenshot displays two windows from the IUCLID5 interface. The top window, titled "Legal entity: European Chemicals Agency / Helsinki / Finland", has tabs for "General information", "Identifiers", "Contact information", and "Sites". The "General information" tab is active, showing fields for "Legal entity name" (European Chemicals Agency), "Legal entity type", and "Remarks".

The bottom window, titled "Information", has tabs for "Access", "Consultation", "Attachments", "Annotations", and "Validation". The "Information" tab is active, showing a "Type" dropdown set to "Legal entity". Below this, the "UUID" field is highlighted with a red box and contains the value "IUC5-22". The "Dossier UUID" field contains "0". At the bottom, there are checkboxes for "Sealed", "Copy protected", "Subset of original", and "Official entry (LEO)", with the last one checked.

## 2. LE in IUCLID5 Dossier Header

- When creating the dossier you must ensure that you use the IUCLID5 User Account for the correct legal entity.
- This legal entity is visible at the bottom of IUCLID5 main screen.



## 2. LE in IUCLID5 Dossier Header

- How to find the legal entity that is “creating” the dossier?
- Click on “Legal entity” on the IUCLID5 main screen.

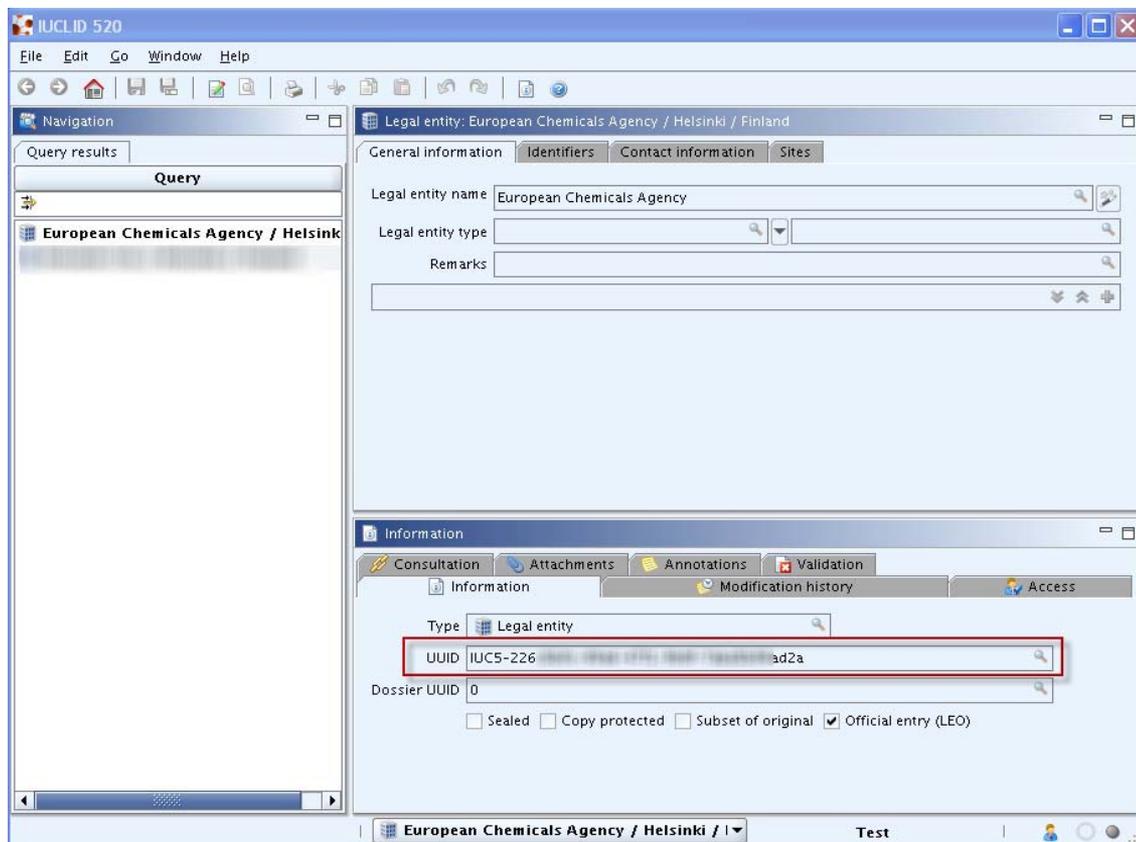


- Choose the same legal entity from the query list that you have seen at the bottom of the main screen previously.



## 2. LE in IUCLID5 Dossier Header

3. In the “*Information*” field, under the “*Information*” tab, you can find the UUID of the legal entity selected to create the dossier.



# 3. LE in REACH-IT

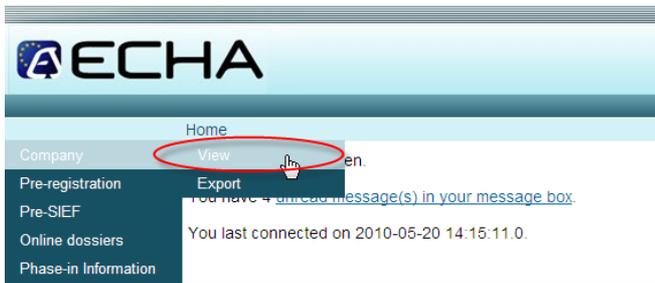
- The account you use in REACH-IT will determine the legal entity that ECHA will consider as associated with all the regulatory processes and/or communications concerning the submitted dossier.
  - How to enter the correct submitting legal entity in REACH-IT?
1. When you login in on your REACH-IT account



The screenshot shows the ECHA REACH-IT login interface. At the top is the ECHA logo. Below it is a 'Login' section with the instruction 'Please provide your login information to enter REACH-IT'. A note states 'Fields marked with an asterisk (\*) are mandatory.' The login form includes three mandatory fields: 'User ID', 'Password', and 'Enter the text shown:'. The 'Enter the text shown:' field contains a CAPTCHA image of the word 'wzsgfu' and a '?' icon. Below the CAPTCHA is a link that says 'Can't read the text below? [Try another](#)'. At the bottom of the form are 'Connect' and 'Cancel' buttons. Below the form is a link for 'Forgot your user ID or password?'.

# 3. LE in REACH-IT

2. If you point to “Company” and click on “View”



3. The second row in the “General information” field contains the UUID of the REACH-IT submitting legal entity.

General information	
Party Name	<a href="#">Print</a>
UUID	ECHA-12eecf3c-1111-1111-1111-111111111111-124
D-U-N-S number:	
VAT number:	
Remarks:	

- **Please when creating your dossier make sure that the legal entity indicated in the dossier header and in section 1.1 of your IUCLID 5 dossier is matching with the one used to submit the dossier in REACH-IT.**

***Thank you for your attention!***