

Most Common Reasons for Failing Business Rules Verification

REACH 2013- Act Now!
Webinars

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Most common reasons for failing Business Rule verification

- Joint submission information – BR027, BR091
- Change of Tonnage Band – BR082
- Legal Entity Inconsistency – BR131
- Substance Identification – BR020, BR053
- IUCLID 5 fields/template – BR035, BR164, BR024, BR040

Business Rules Related to Joint Submissions



BR027 & BR091 - Joint Submission

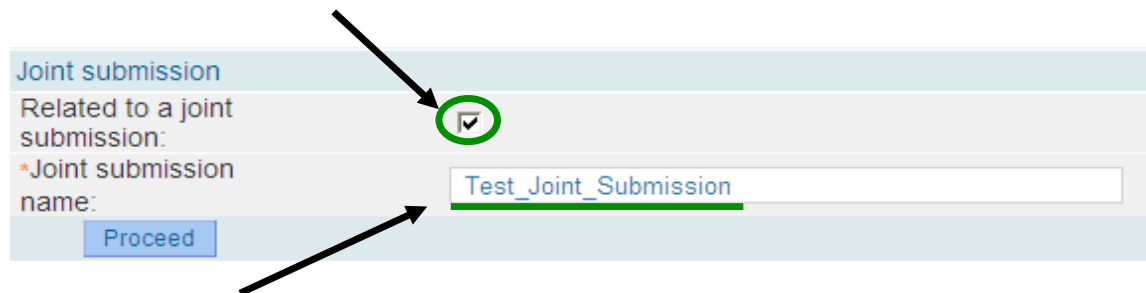
- The following type of submissions are possible:
 - Individual Submission
 - Joint Submission (JS)
 - REACH-IT Joint Submission Object (JSO)
 - Company role (lead, members)
 - Lead Registrant
 - Create the Joint Submission Object in REACH-IT and distribute token
 - Member Registrant
 - Confirm their role in the Joint Submission via REACH-IT

BR027 – JS information incorrect

- 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**.

BR027 - No JS indicated

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



Joint submission
Related to a joint submission:
*Joint submission name:
Proceed

- 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.

BR027 - No JS indicated

- REACH-IT allows you to consult your role in a JS. From your REACH-IT home page, click on **<Joint Submission>** and on **<view joint submission>**.

[Home](#) > [View Joint Submissions](#)

[Add new joint submission](#)

Joint Submission criteria

Joint submission name:

Substance identity criteria

EC number:

CAS number:

Chemical Name:

BR027 – Substance Identification (SID)

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


Substance identification


[231-791-2] water

EC Number 231-791-2	CAS Number 7732-18-5	Name water
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- Please ensure that the information is identical to what you are indicating in your IUCLID 5 section 1.1:

Reference substance

Reference substance flags 

 water / water / 7732-18-5

EC number 231-791-2	EC name water
CAS number 7732-18-5	CAS name
IUPAC name water	

BR091 – Information provided by the Lead

- 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 is providing on their behalf.



The screenshot shows a web form titled "Type of submission". It includes a checked checkbox for "Joint submission" and a table for "Data selected for opt-out" with columns for "Document", "Section", and "Justification...". Below the table is a "Go to link target" button. A red box highlights the section "Information provided by the lead on behalf of the member(s)", which contains three checkboxes: "Chemical safety report" (unchecked), "Guidance on safe use" (checked), and "Review by an assessor" (unchecked).

Type of submission

Joint submission

Data selected for opt-out

Document	Section	Justification...
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[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 - Information provided by the Lead

- BR091 checks that what the members indicate in their dossier what is 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 a 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.

Business Rule Related to Tonnage Band



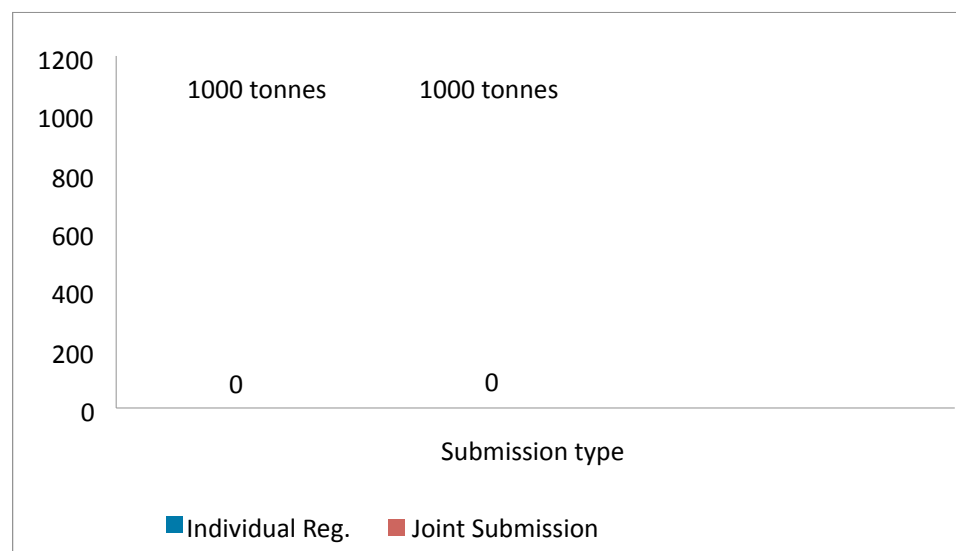
BR082 - Change of tonnage band

- **BR082** checks if the information concerning the registration tonnage band(s) is differing from the latest successful submission for the same substance.

What counts as change of tonnage band?

- Changes in the production/import volume/use
- A change from a Standard Registration Template to an Intermediate Template, or vice versa.
- A change from an (already submitted) Individual Submission to a Joint Submission.

BR082 - Change of tonnage band



A change from an (already submitted) Individual Submission to a Joint Submission, is by default **a change in the tonnage band.**

BR082 - Change of tonnage band

- Most common mistakes related to BR082:
 - The registrant changes from a Standard Registration Template to an Intermediate Template, or vice versa, without indicating “change of tonnage band” in the IUCLID5 Dossier Header (spontaneous update – usually NONS);
 - A previously individual registrant (i.e. has already submitted a dossier without referring to any Joint Submission), joins a Joint Submission for the same substance (spontaneous update), but does not indicate “change of tonnage band” in the IUCLID5 Dossier Header.

BR082 - Change of tonnage band

- Should you be in any of the previously described situations, you should keep it in mind, that as (one of) your update reason(s) “change of tonnage band” must be indicated in order to pass the Business Rule verification.

Specific submissions

The submission is an update

Last submission number AA004XXX-00

Reason for updating

Further to a request/decision from regulatory body

Spontaneous update

change of tonnage band

Justification change of tonnage band

Remarks The change of tonnage.....

Business Rule Related to Legal Entity



BR131 - Legal Entity inconsistency

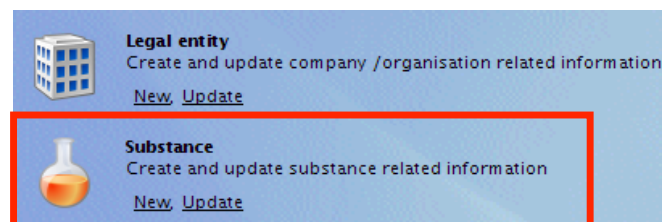
- Legal entities (LE) are essential for ECHA to ensure that the identity of the registrant can be confirmed during any regulatory process.
- In the process of creating a dataset, making a dossier and submitting the dossier to ECHA via the REACH-IT application, there are three instances where the legal entity needs to be indicated and kept consistent:

- 1. IUCLID 5 Section 1.1 (*'Substance Identification'*)**
- 2. IUCLID 5 Dossier Header**
- 3. REACH-IT**

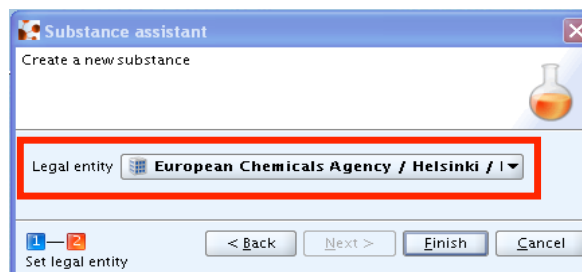
LE in the Substance Dataset

In IUCLID 5 Section 1.1 (*'Substance Identification'*) the substance dataset is linked to a specific legal entity.

1. Click on new under the *"Substance"* section in the IUCLID 5 main screen.



2. Then enter the substance name (e.g. *Test_Substance_1*) and select the LEGAL ENTITY you wish to associate with your substance dataset.



LE in the Substance Dataset

3. You will be able to see the LE associated with your substance dataset in IUCLID 5 Section 1.1 (*Substance Identification*).



The screenshot shows the IUCLID 5 interface for 'Substance identification'. The left sidebar shows a tree view with '1.1 Identification' selected. The main panel displays the following fields:

- Chemical name: Test_Substance_1
- Public name: (empty)
- Legal entity flags: (empty)
- Legal entity: European Chemicals Agency / Helsinki / Finland
- Third party flags: (empty)
- Third party: (empty)

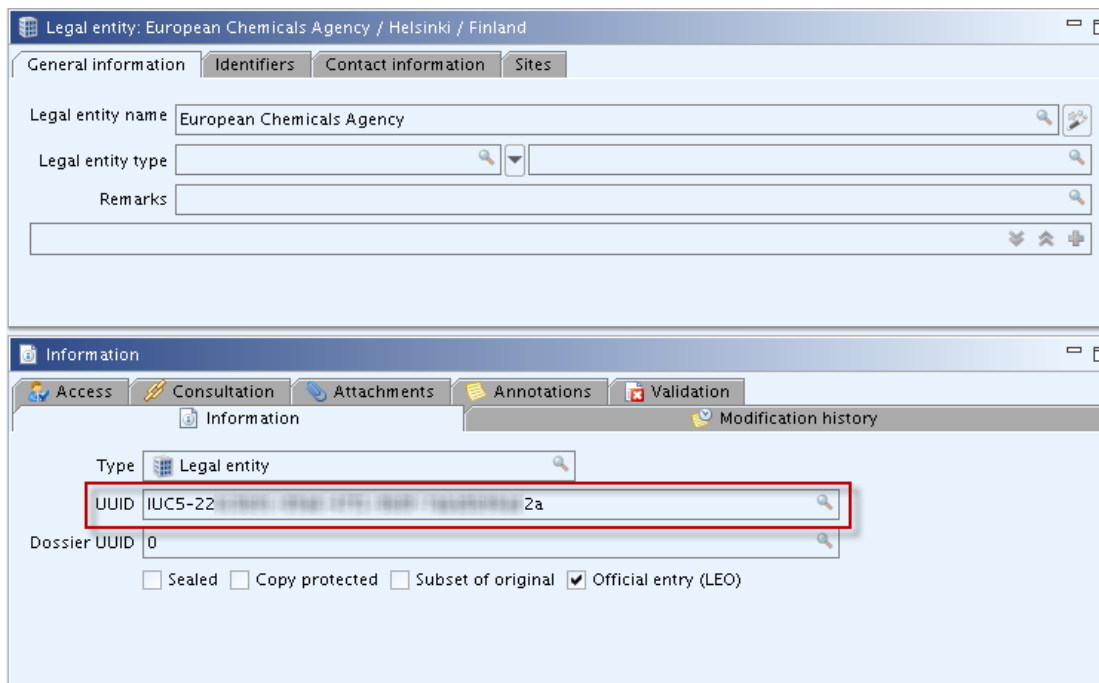
Below these fields is the 'Role in the supply chain' section with role flags: Manufacturer, Importer, Only representative, Downstream user.

A red box highlights the 'Third party' field. A black circle highlights the blue arrow icon on the right side of the 'Legal entity' field, with an arrow pointing to it from the text below.

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.

LE in the Substance Dataset

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

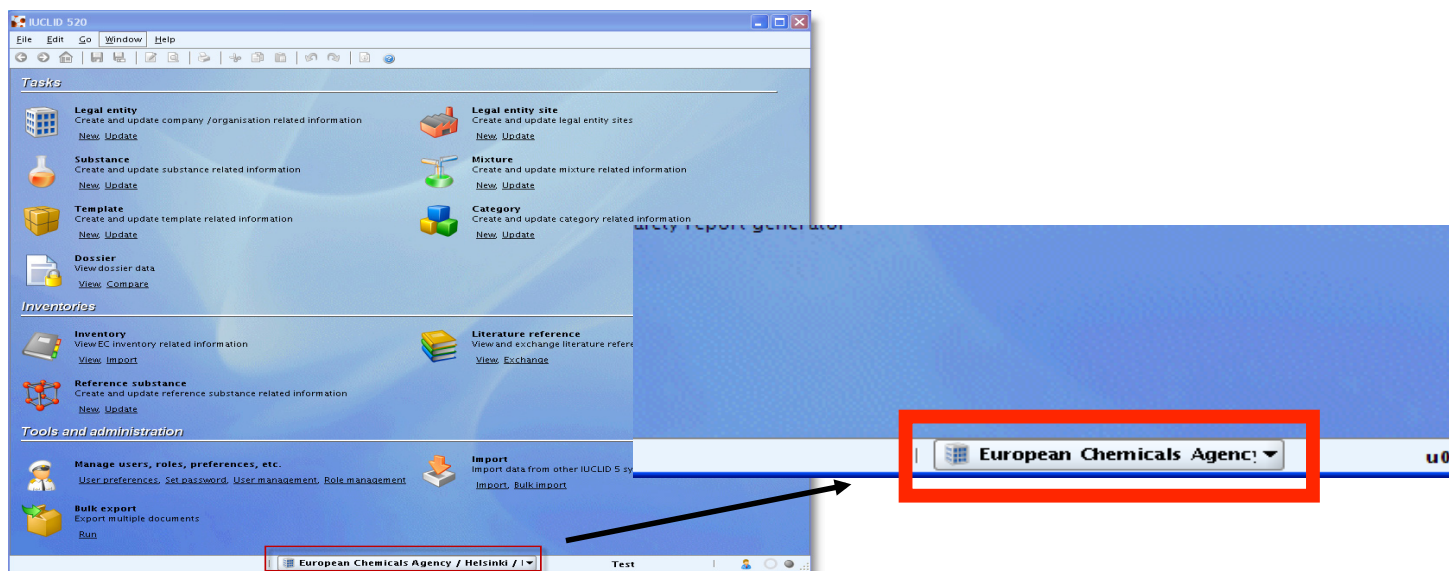


The screenshot displays two windows from the ECHA Substance Dataset interface. The top window, titled "Legal entity: European Chemicals Agency / Helsinki / Finland", has tabs for "General information", "Identifiers", "Contact information", and "Sites". The "General information" tab is active, showing 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 "IUC5-22-00000000-0000-0000-0000-000000000000 2a". The "Dossier UUID" field contains the value "0". At the bottom, there are checkboxes for "Sealed", "Copy protected", "Subset of original", and "Official entry (LEO)", with the last one checked.

LE in the IUCLID 5 Dossier Header

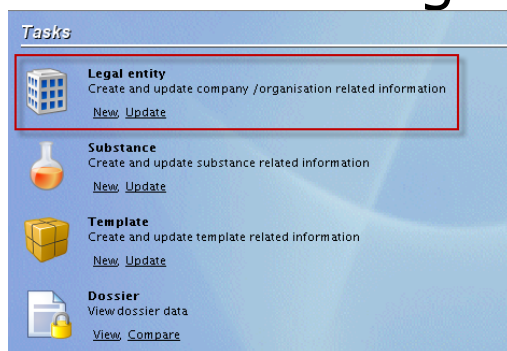
- When creating the dossier you must ensure that you use the IUCLID 5 User Account for the correct legal entity.
- The legal entity that is in use is visible at the bottom of IUCLID 5 main screen.



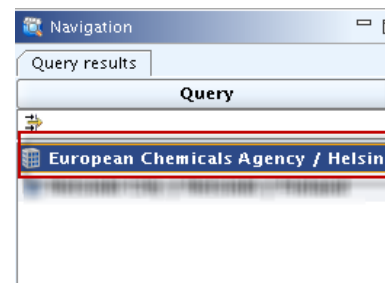
LE in the IUCLID 5 Dossier Header

How to find the Legal entity that is “creating” the dossier?

1. Click on “Legal entity” on the IUCLID 5 main screen.

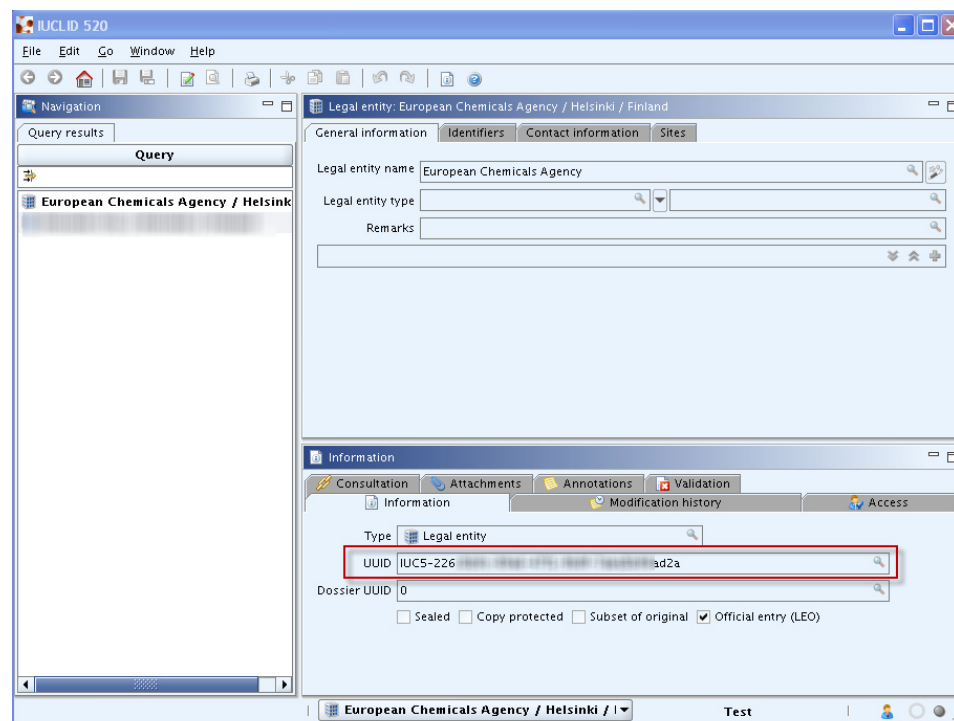


2. Choose the same legal entity from the query list that you have seen at the bottom of the main screen previously.



LE in the IUCLID 5 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.



Legal Entity 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.

1. When you login in on your REACH-IT account

Login

Please provide your login information to enter REACH-IT


Fields marked with an asterisk () are mandatory.*

* User ID:

* Password:

* Enter the text shown: ?

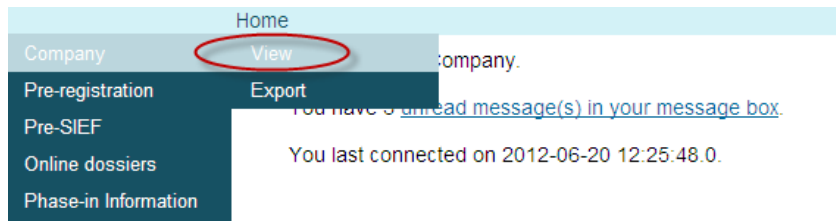
Can't read the text below? [Try another](#)



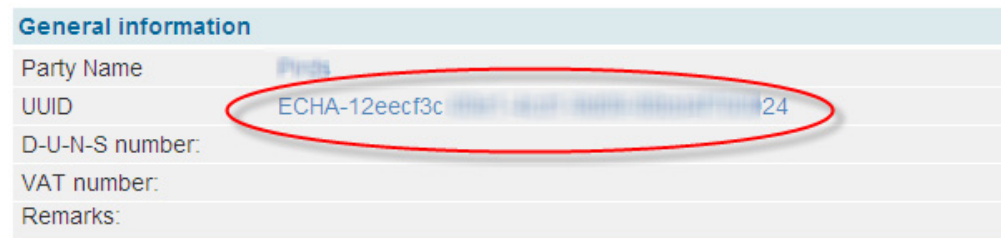
[Forgot your user ID or password?](#)

Legal Entity 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.



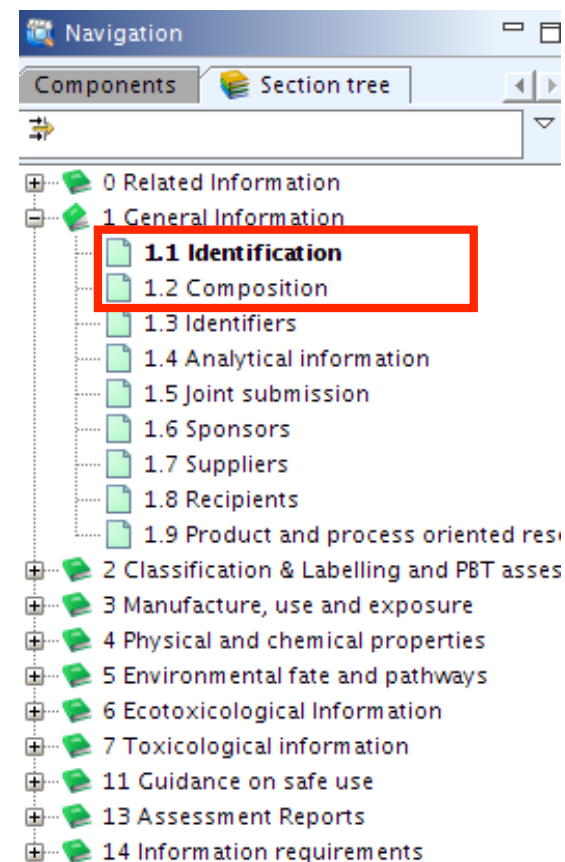
Please note when creating your dossier make sure that the legal entity indicated in the dossier header and in section 1.1 of your IUCLID 5 dossier is matching with the one used to submit the dossier in REACH-IT.

Business Rules Related to Substance Identification



BR020 - Substance Identification

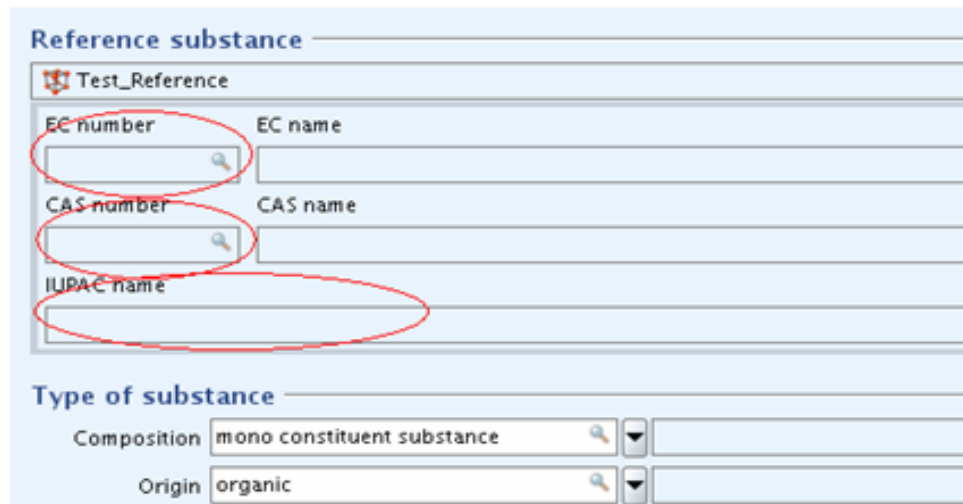
- What REACH-IT checks?
Section 1.1 (Substance Identification) & section 1.2 (Substance Composition) of the IUCLID 5 dossier
- Why?
Clear understanding of the substance submitted in order to be processed accordingly



BR020 - Substance Identification

- **BR020** checks that either an EC number **or** a CAS number **or** a IUPAC name is provided in the corresponding IUCLID 5 fields (Sections 1.1 and 1.2), for each reference substance.

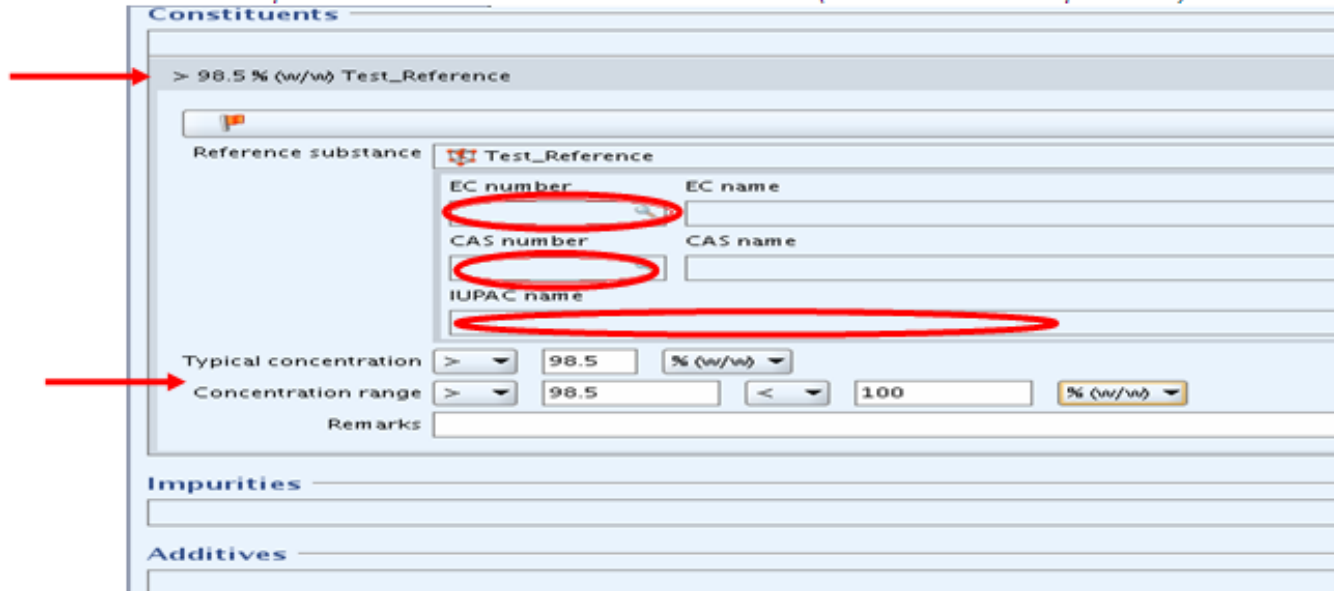
Example of failure in IUCLID 5 Section 1.1 (Substance Identification):



The screenshot shows the 'Reference substance' section of the IUCLID 5 form. It includes a 'Test_Reference' icon and three input fields: 'EC number', 'CAS number', and 'IUPAC name'. All three fields are empty and circled in red. Below these fields is the 'Type of substance' section, which contains two dropdown menus: 'Composition' (set to 'mono constituent substance') and 'Origin' (set to 'organic').

BR020 - Substance Identification

➤ *Example of failure in IUCLID 5 Section 1.2 (Substance Composition)*



Constituents	
> 98.5 % (w/w) Test_Reference	
Reference substance	Test_Reference
EC number	
CAS number	
IUPAC name	
Typical concentration	> 98.5 % (w/w)
Concentration range	> 98.5 < 100 % (w/w)
Remarks	
Impurities	
Additives	

➔ **EC# or CAS# or IUPAC name** should be provided in all the related fields of Section 1.2 (including the Impurities and Additives, if any)

BR053 – EC# vs. Inquiry Result

- **BR53** checks that the EC number in section 1.1 is the same, as the result of the indicated inquiry notification in section 1.3.

How to pass **BR053**?

- When submitting your dossier, indicate your EC number in IUCLID 5 section 1.1 and your correct inquiry number in section 1.3. Choose 'REACH inquiry number' from the drop-down list and insert your inquiry number in to the corresponding field.

BR053 – EC# vs. Inquiry Result

COMMUNICATION RELATING TO YOUR INQUIRY UNDER REGULATION (EC) NO 1907/2006

In accordance with Article 12(2) of Regulation (EC) No 1907/2006 (“the REACH Regulation”) the European Chemicals Agency (ECHA) has received your inquiry dossier for [REDACTED] with **EC number** [REDACTED].

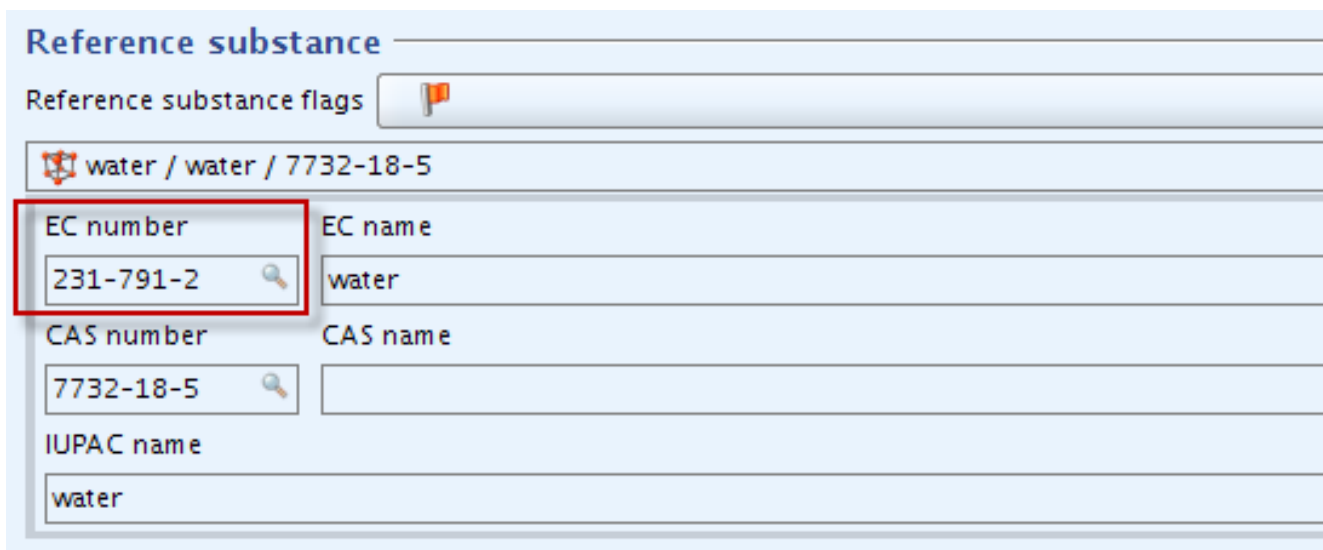
ECHA has assigned an inquiry number as follows:

Inquiry number is 06- [REDACTED].


You are required to include the inquiry number in your registration dossier.

BR053 – EC# vs. Inquiry Result

- Link your EC number to section 1.1 of your IUCLID 5 dossier.



The screenshot shows a web form for entering reference substance information. The form is titled "Reference substance" and includes several input fields. The "EC number" field is highlighted with a red box and contains the value "231-791-2". The "EC name" field contains "water". The "CAS number" field contains "7732-18-5". The "CAS name" field is empty. The "IUPAC name" field contains "water".

Reference substance	
Reference substance flags 	
water / water / 7732-18-5	
EC number	EC name
231-791-2	water
CAS number	CAS name
7732-18-5	
IUPAC name	
water	

- Format of EC number: XXX-XXX-X.

BR053 – EC# vs. Inquiry Result

- Indicate your inquiry number in section 1.3 of your IUCLID 5 dossier

Identifiers

Regulatory programme identifiers

Flags	Regulatory programme	ID ▲	Remarks
EU: REACH	REACH registration number		
EU: REACH	REACH inquiry number		
EU: REACH	notification number (NCD)		

- Format of inquiry number: 06-XXXXXXXXXX-XX-XXXX.

Business Rules Related to Various IUCLID fields and IUCLID Templates



BR035 – Latest submission number

- **BR035** checks that if **you submit an update dossier**, the last submission number in the dossier header is the correct one
- The last submission number given in the dossier header must be the same as the submission number of the latest successful submission. Successful submission means here that the business rules have been passed and that a registration number has been issued for it
- If update is requested due to failure in Technical Completeness Check (TCC) you must use the submission number of the submission that failed at the TCC step

BR035 – Latest submission number

- **How to pass BR035?**
- When updating your submission, indicate your last submission number in the appropriate field in your IUCLID 5 dossier header during the dossier creation.
- Format of submission number **AAXXXXXX-XX**

Specific submissions

The submission is an update

Last submission number

Reason for updating

Further to a request/decision from regulatory body

Spontaneous update

BR035 – Latest submission number

- Only after a submission has passed the business rules verification step, can it's submission number be referred to as "previous submission number"!
- Inquiry notifications are not part of the registration processing, and as such, submission numbers of inquiries can not be used as "previous submission numbers". You may however need to use your inquiry number in section 1.3 of your dossier.

BR164 – Result of PBT Assessment

- **BR164** checks that if a CSR is needed, the outcome of the a PBT assessment is provided in section 2.3 of your IUCLID 5 dossier.

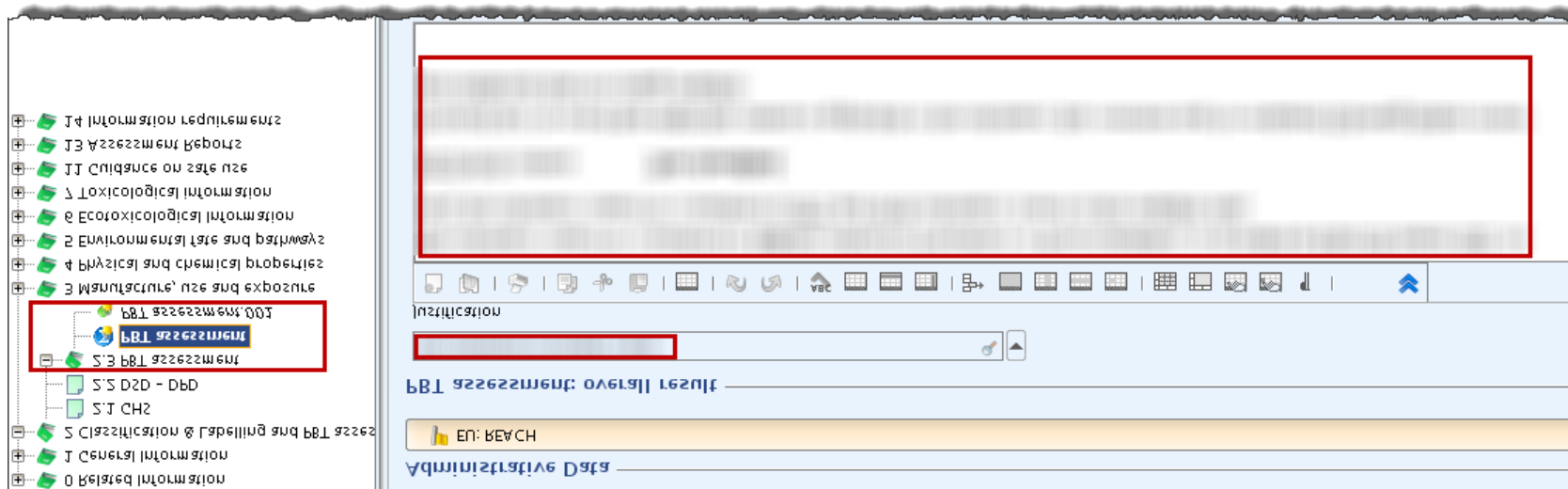
Chemical Safety Report (CSR) is required in the following cases:

- Individual dossier above 10 tonnes / year
- Members above 10 tonnes a year, who are NOT relying on the CSR provide by the lead
- Lead registrants above 10 tonnes a year OR, regardless of their tonnage band, if they declare that they are providing the CSR on behalf of their members

BR164 – Result of PBT Assessment

How to pass **BR164**?

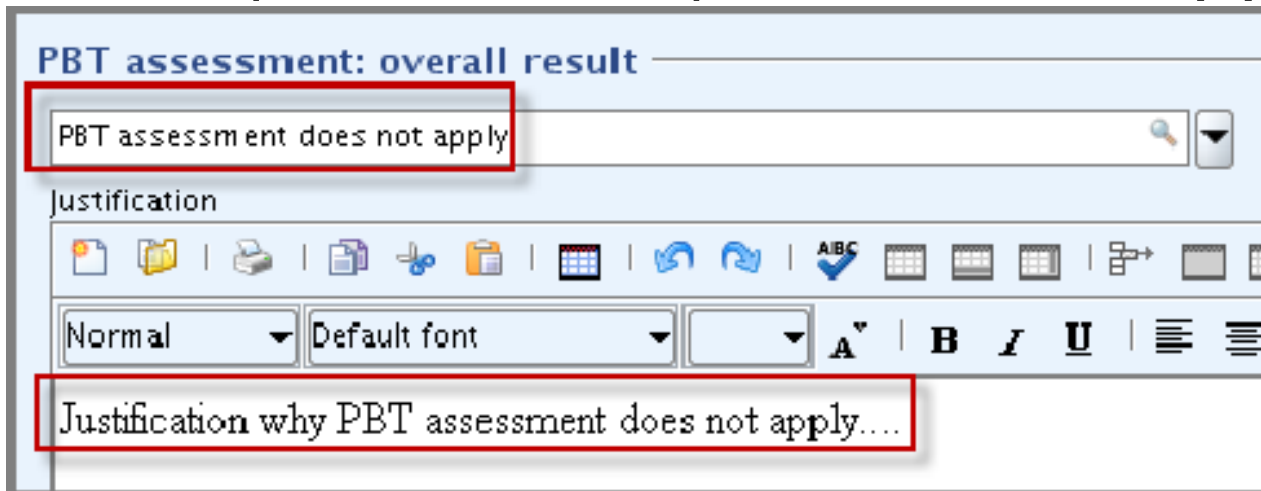
- During the creation of the substance dataset, an endpoint summary must be created, and a selection must be made from the drop-down list under 'PBT assessment: overall result'.



The screenshot displays the ECHA database interface. On the left, a tree view shows the 'PBT assessment' section highlighted in red. The main panel on the right shows a form with a red box around the 'PBT assessment: overall result' field, which is currently set to 'EU: REACH'. Below this, the 'Administrative Data' section is visible.

BR164 – Result of PBT Assessment

- In case registrant selects “PBT assessment does not apply” from the drop-down list, a justification must be provided to explain the reason(s).

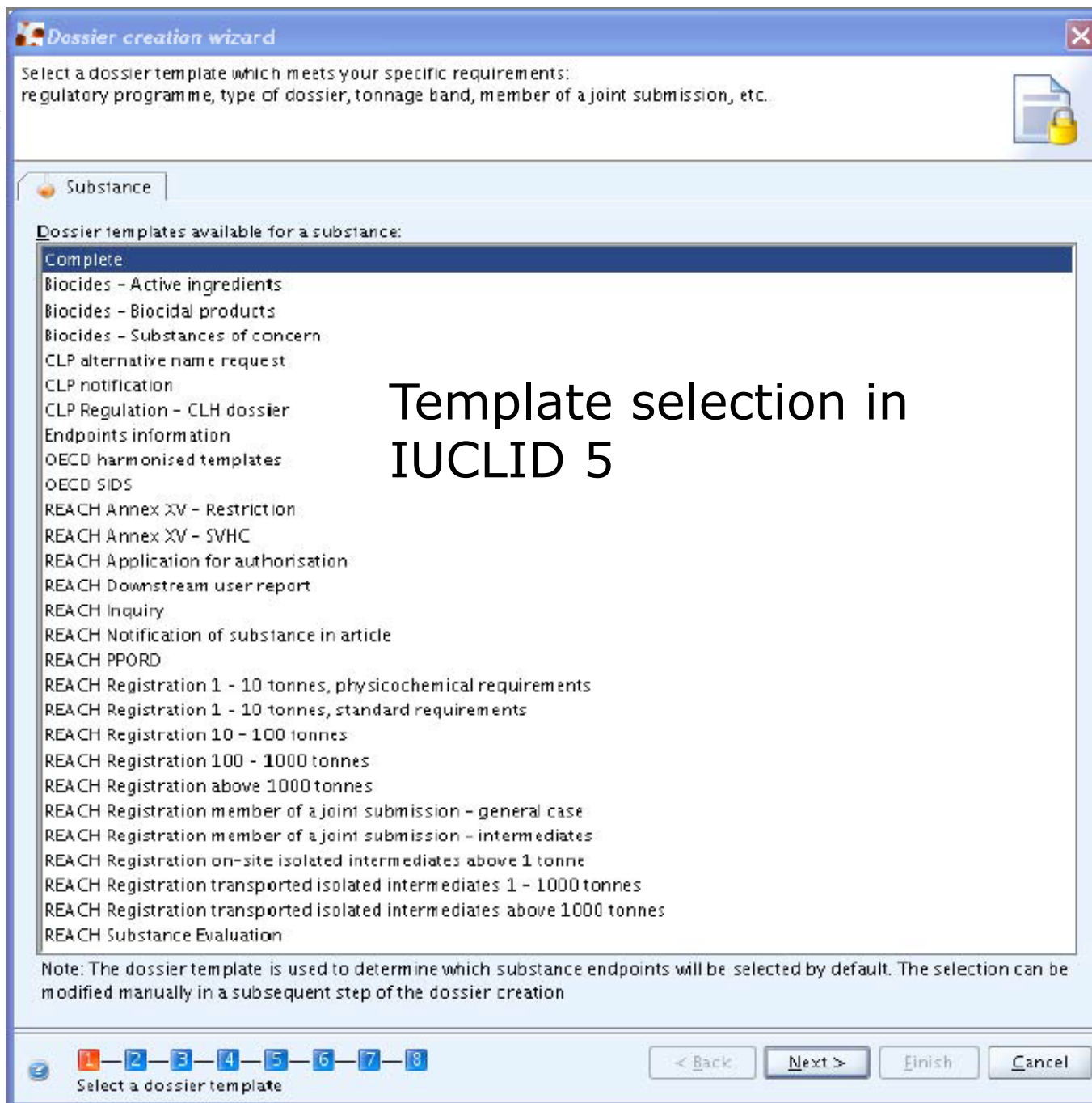


The screenshot shows a web form titled "PBT assessment: overall result". A dropdown menu is open, showing the selected option "PBT assessment does not apply". Below the dropdown is a "Justification" section with a rich text editor toolbar. The text area contains the text "Justification why PBT assessment does not apply...".

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.

BR024 – Correct IUCLID Template

- **BR024** checks that the selected IUCLID 5 template corresponds with the submission type indicated in REACH-IT during the submission process.



Dossier creation wizard

Select a dossier template which meets your specific requirements:
regulatory programme, type of dossier, tonnage band, member of a joint submission, etc.

Substance

Dossier templates available for a substance:

- Complete
- Biocides - Active ingredients
- Biocides - Biocidal products
- Biocides - Substances of concern
- CLP alternative name request
- CLP notification
- CLP Regulation - CLH dossier
- Endpoints information
- OECD harmonised templates
- OECD SIDS
- REACH Annex XV - Restriction
- REACH Annex XV - SVHC
- REACH Application for authorisation
- REACH Downstream user report
- REACH Inquiry
- REACH Notification of substance in article
- REACH PPORD
- REACH Registration 1 - 10 tonnes, physicochemical requirements
- REACH Registration 1 - 10 tonnes, standard requirements
- REACH Registration 10 - 100 tonnes
- REACH Registration 100 - 1000 tonnes
- REACH Registration above 1000 tonnes
- REACH Registration member of a joint submission - general case
- REACH Registration member of a joint submission - intermediates
- REACH Registration on-site isolated intermediates above 1 tonne
- REACH Registration transported isolated intermediates 1 - 1000 tonnes
- REACH Registration transported isolated intermediates above 1000 tonnes
- REACH Substance Evaluation

Note: The dossier template is used to determine which substance endpoints will be selected by default. The selection can be modified manually in a subsequent step of the dossier creation

1 2 3 4 5 6 7 8
Select a dossier template

< Back Next > Finish Cancel

Template selection in IUCLID 5


BR024 – Correct IUCLID Template

- How to pass **BR024**?
- Before exporting the data you have to make sure that the template selected corresponds with the intended submission (e.g. correct dossier type (Inquiry, PPOrd, Registration, etc.), correct tonnage band).
- There is no specific template available for “lead” of Joint Submission, as for those cases the generic registration templates (both general and intermediate) should be used. The information about the joint submission has to be indicated in those cases in the dossier header.
- Note that in the case of a lead dossier in a Joint Submission, the template used indicates the tonnage band of the joint submission and not the tonnage band of the registration of the lead registrant.

BR040 – Correct Reference Number

- **BR040** checks that if an update dossier is submitted, the quoted reference number in section 1.3 of IUCLID 5 is the right one, referring to the correct registration.
- This reference number is the one you have received after successfully submitting your dossier to ECHA.

The registration was considered complete.

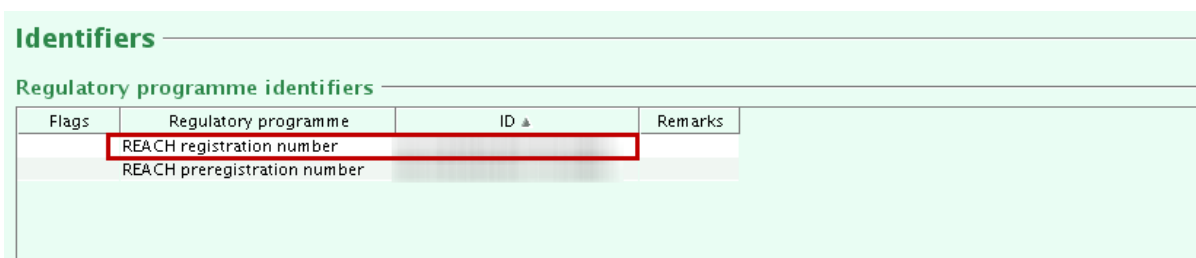
The registration number for this registration: **01-** 

The registration date for this registration: **04 October 2012**

BR040 – Correct Reference Number

How to pass **BR040**?

- When updating your dossier, you will need to indicate the correct reference number in your IUCLID 5 dossier in section 1.3. Choose 'REACH registration number' from the drop-down list and insert your registration number into the corresponding field.



Identifiers

Regulatory programme identifiers

Flags	Regulatory programme	ID ▲	Remarks
	REACH registration number		
	REACH preregistration number		

Format of the registration number: **01**-XXXXXXXXXX-XX-XXXX

Thank You

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