

Agenda

- Introduction 5 min
- Presentation #1: IUCLID new user interface and its key functionalities (35 min)
- Presentation #2: Completeness check and manual verification areas (40 min)
- Questions (10 min)



New IUCLID user interface

Main functionalities

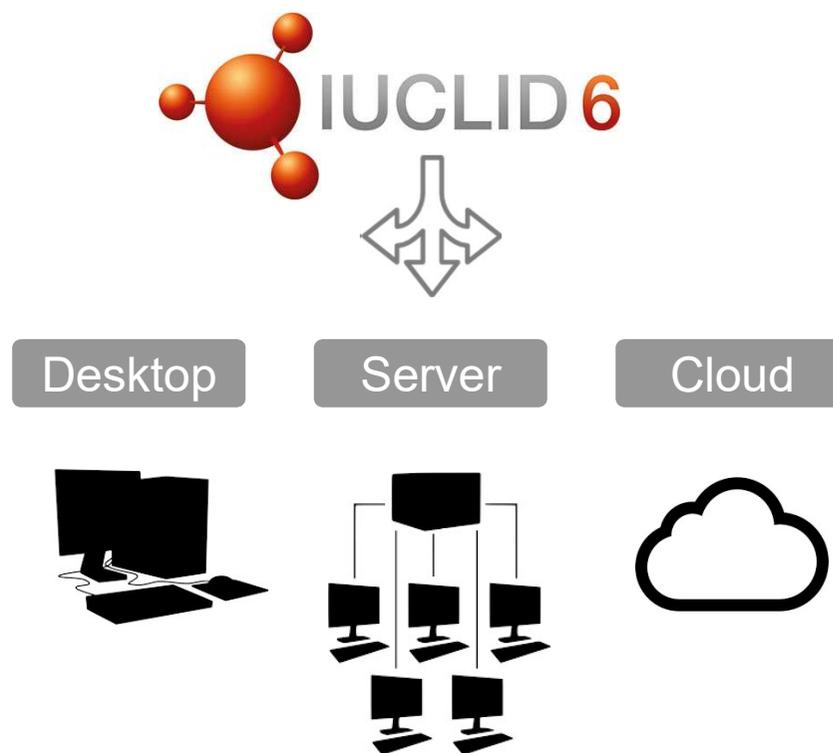
12 June 2019

Margot Mägi

Data Availability Unit
ECHA

Different distributions of IUCLID

- Desktop - for single user, on own computer
- Server - hosted on a server, shared with multiple users
- Cloud - ECHA Cloud Services, hosted by ECHA, for REACH and CLP users

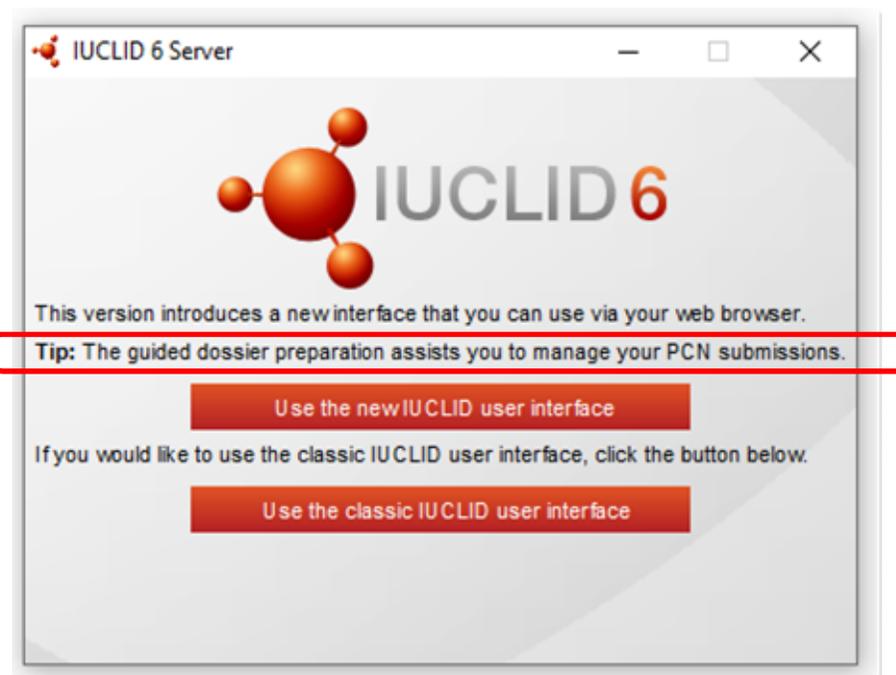


IUCLID Web user interface

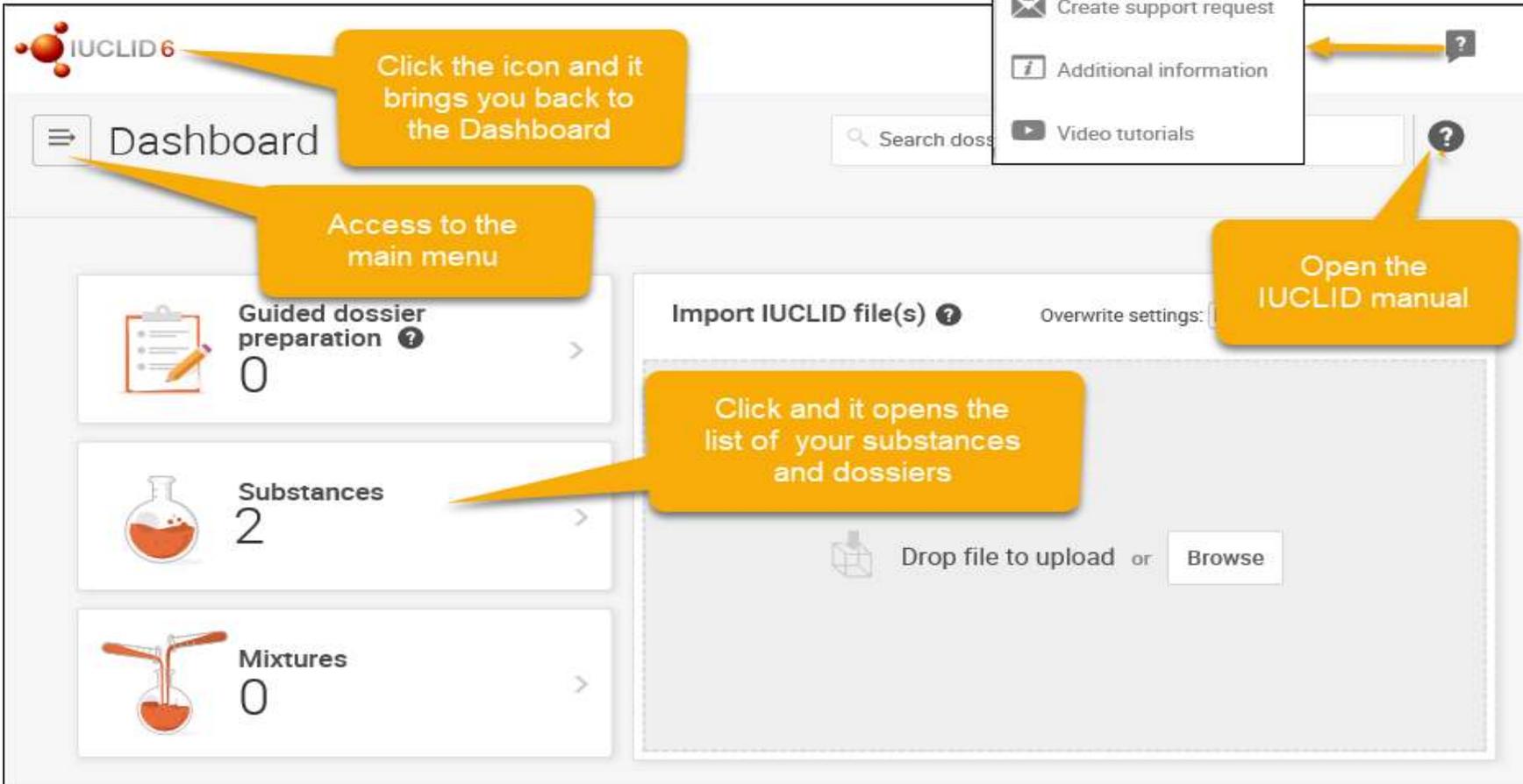
- Available since November 2018, IUCLID version 6.3
- Available for server and desktop IUCLID
- Look and feel the same as in IUCLID Cloud

What is the pre-launch screen

- Swift between the classic and the web interface
- If closed, it triggers exiting IUCLID
- A new tip is displayed with every launch



Dashboard / home page



The screenshot shows the IUCLID 6 dashboard interface. At the top left is the IUCLID 6 logo. Below it is a 'Dashboard' button with a hamburger menu icon. To the right is a search bar labeled 'Search dossier'. Further right is a help menu with options: 'Q&A', 'Create support request', 'Additional information', and 'Video tutorials'. The main content area on the left contains three summary cards: 'Guided dossier preparation' with 0 items, 'Substances' with 2 items, and 'Mixtures' with 0 items. On the right is a section for 'Import IUCLID file(s)' with an 'Overwrite settings' option and a 'Browse' button. Several orange callout boxes provide instructions: one points to the IUCLID 6 logo, another to the 'Dashboard' button, a third to the 'Substances' card, a fourth to the 'Import IUCLID file(s)' section, and a fifth to the help menu.

IUCLID 6

Click the icon and it brings you back to the Dashboard

Dashboard

Search dossier

Q&A

Create support request

Additional information

Video tutorials

Access to the main menu

Guided dossier preparation 0

Substances 2

Mixtures 0

Import IUCLID file(s) ? Overwrite settings: []

Click and it opens the list of your substances and dossiers

Drop file to upload or Browse

Open the IUCLID manual

View dossiers /go to source

Brings you to the list of all dossiers created from this substance dataset

Substance information

Substance name: Training_substance_1

IUPAC name:

Legal entity: Test Company

CAS number:

[View Dossiers](#)

Dossier versions X

Training dossier3			27/05/2019 19:04	...
Subject name	Training_substance_1	Submission type	REACH Registration member of a joint submission - general case	
🔒				
Training dossier 2			27/05/2019 19:02	...
Subject name	Training_substance_1	Submission type	REACH Registration member of a joint submission - general case	
🔒				
			18:57	...
			joint	
🔒				

Substance information

Substance name: Training_substance_1

IUPAC name:

Legal entity:

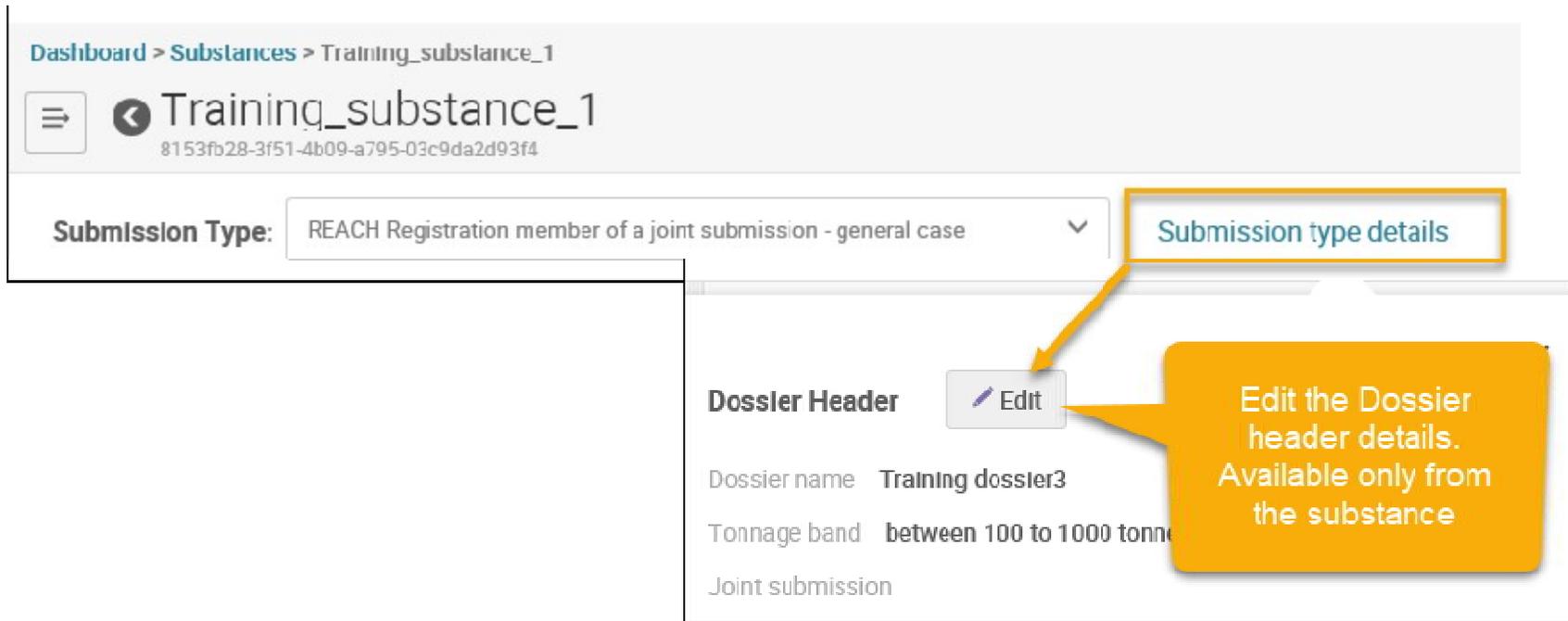
CAS number:

[View Dossiers](#)

[Go to source](#) →

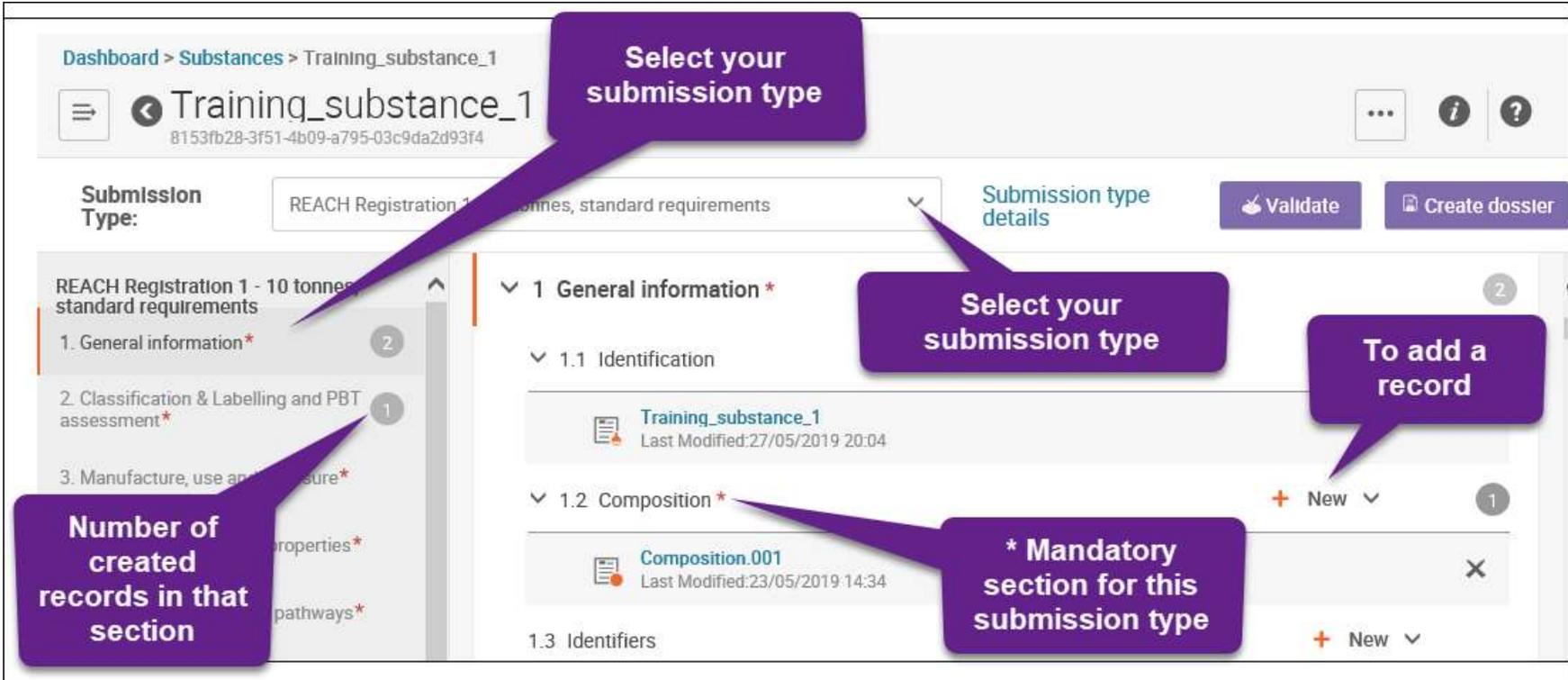
Brings you to the substance dataset. This option is only available from inside a dossier.

Dossier header



The screenshot shows the ECHA dossier header interface. At the top, there is a breadcrumb trail: **Dashboard > Substances > Training_substance_1**. Below this, the substance name **Training_substance_1** is displayed with a unique identifier **8153fb28-3f51-4b09-a795-03c9da2d93f4**. A dropdown menu for **Submission Type** is set to **REACH Registration member of a joint submission - general case**. A callout box labeled **Submission type details** points to this dropdown. Below the submission type, the **Dossier Header** section is visible, featuring an **Edit** button with a pencil icon. A callout box points to this button with the text: **Edit the Dossier header details. Available only from the substance**. The dossier details shown are: **Dossier name** Training dossier3, **Tonnage band** between 100 to 1000 tonne, and **Joint submission**.

Section tree



The screenshot shows the ECHA REACH registration interface for a substance named "Training_substance_1". The interface includes a breadcrumb trail, a submission type dropdown menu, and a section tree on the left. The section tree lists sections with numbers in circles indicating the count of records. The main content area shows details for selected sections, including "1.1 Identification" and "1.2 Composition", with "New" buttons for adding records. Callouts explain the meaning of the numbers and the asterisk on section names.

Dashboard > Substances > Training_substance_1

Training_substance_1
8153fb28-3f51-4b09-a795-03c9da2d93f4

Submission Type: REACH Registration 1 - 10 tonnes, standard requirements

Submission type details

Validate Create dossier

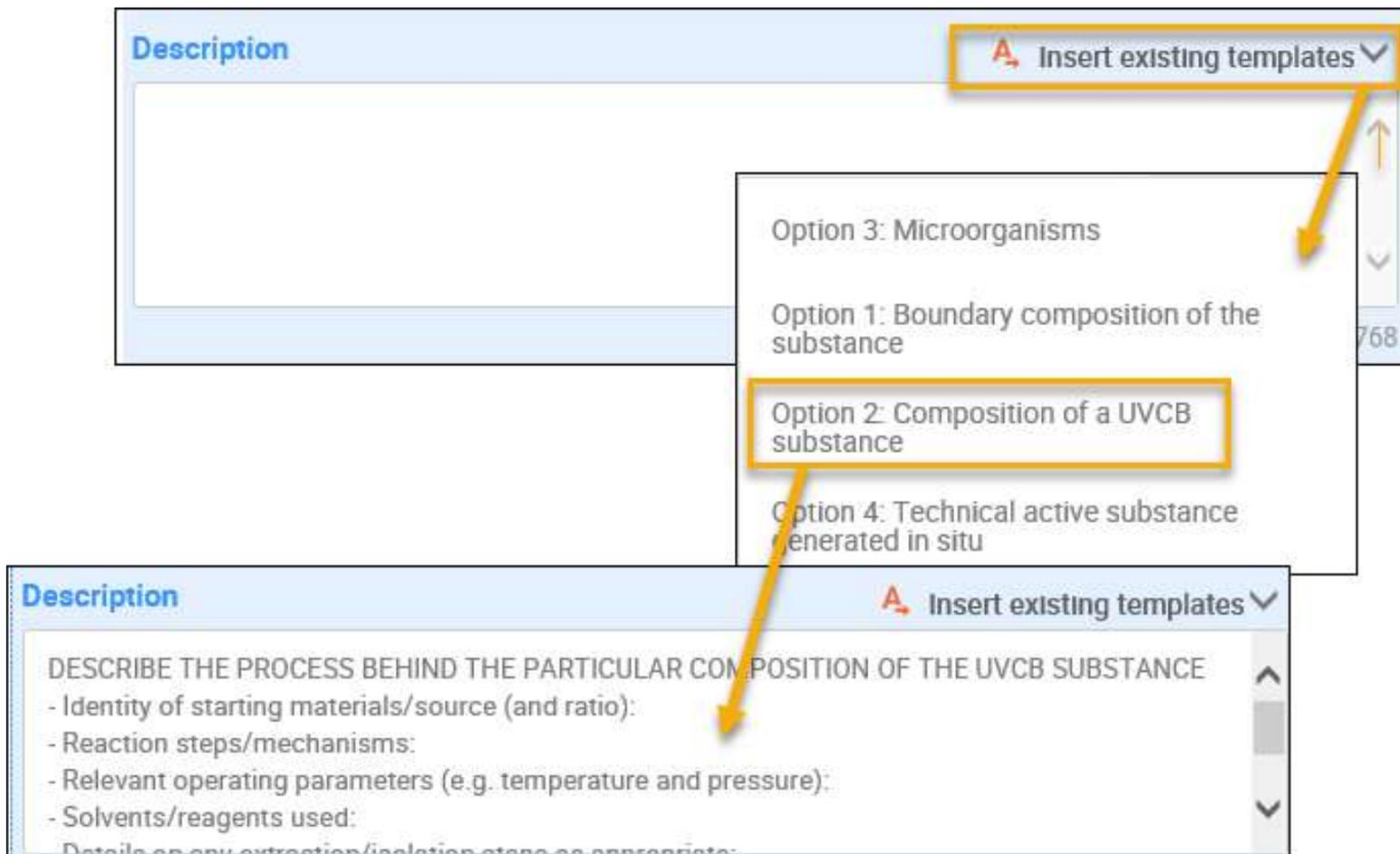
REACH Registration 1 - 10 tonnes, standard requirements

- 1. General information* (2)
- 2. Classification & Labelling and PBT assessment* (1)
- 3. Manufacture, use and exposure* (1)

1 General information *

- 1.1 Identification
 - Training_substance_1 (Last Modified: 27/05/2019 20:04)
- 1.2 Composition* (1)
 - Composition.001 (Last Modified: 23/05/2019 14:34)
- 1.3 Identifiers

Free text template



Description Insert existing templates ▾

- Option 3: Microorganisms
- Option 1: Boundary composition of the substance
- Option 2: Composition of a UVCB substance**
- Option 4: Technical active substance generated in situ

Description Insert existing templates ▾

DESCRIBE THE PROCESS BEHIND THE PARTICULAR COMPOSITION OF THE UVCB SUBSTANCE

- Identity of starting materials/source (and ratio):
- Reaction steps/mechanisms:
- Relevant operating parameters (e.g. temperature and pressure):
- Solvents/reagents used:
- Details on any extraction/isolation steps as appropriate:

Flag



⊗ Degree of purity

None

Set Flags

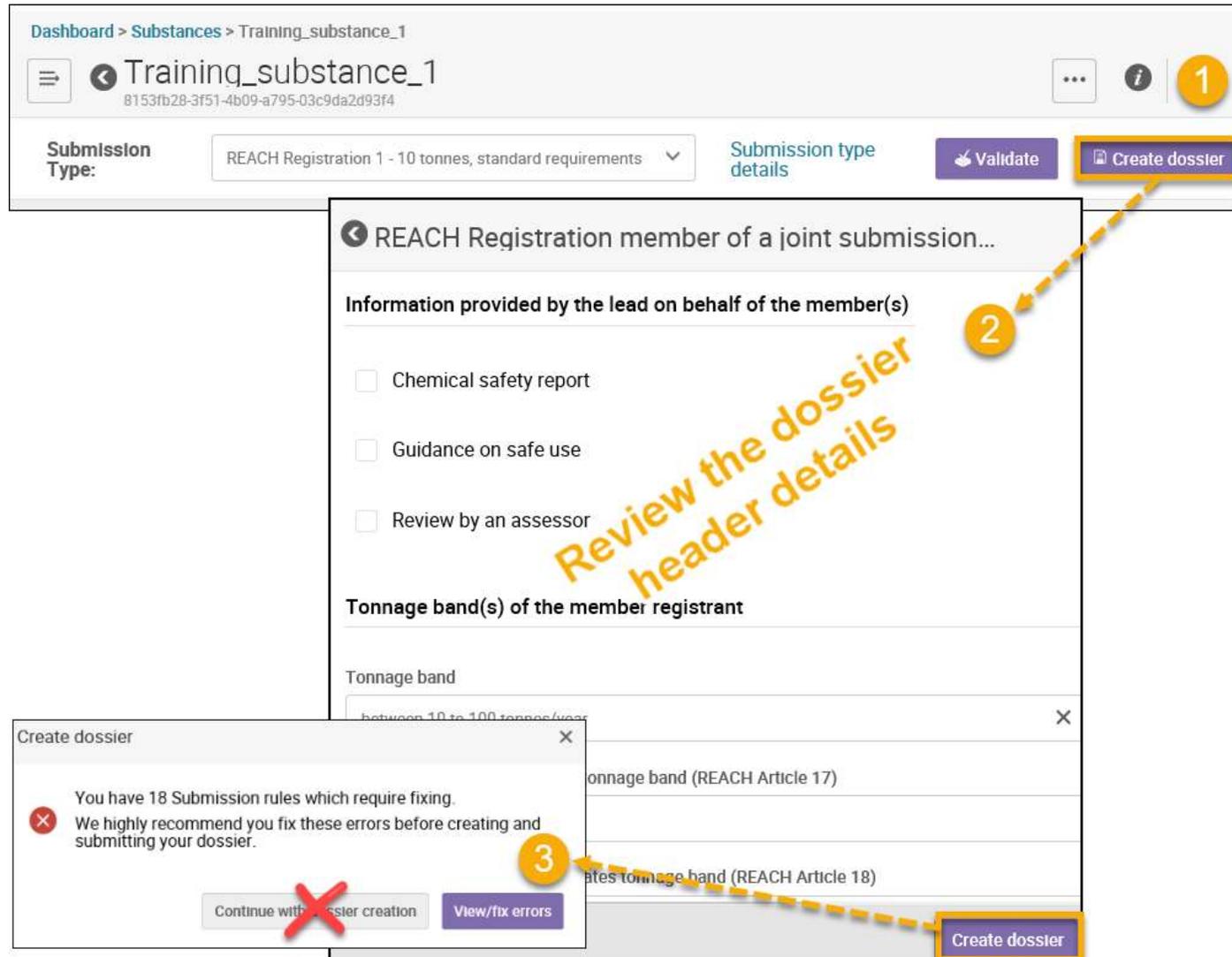
Confidentiality

CBI X v

Justification

A. Insert existing templates

Declaration:
We, [NAME], claim [SHORT SUMMARY OF INFORMATION] confidential in accordance with [RELEVANT REFERENCE TO THE LEGISLATION]).
We, [NAME], hereby declare that, to the best of our knowledge as of today ([DATE]), and in accordance with the due measures of protection that we have implemented, a member of the public should not be able to obtain access to the information claimed confidential without our



Dashboard > Substances > Training_substance_1

Training_substance_1
8153fb28-3f51-4b09-a795-03c9da2d93f4

Submission Type: REACH Registration 1 - 10 tonnes, standard requirements

Submission type details

Validate

Create dossier

REACH Registration member of a joint submission...

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

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

Tonnage band(s) of the member registrant

Tonnage band

between 10 to 100 tonnes/year

tonnage band (REACH Article 17)

tonnage band (REACH Article 18)

Create dossier

You have 18 Submission rules which require fixing.
We highly recommend you fix these errors before creating and submitting your dossier.

Continue with dossier creation

View/fix errors

Create dossier

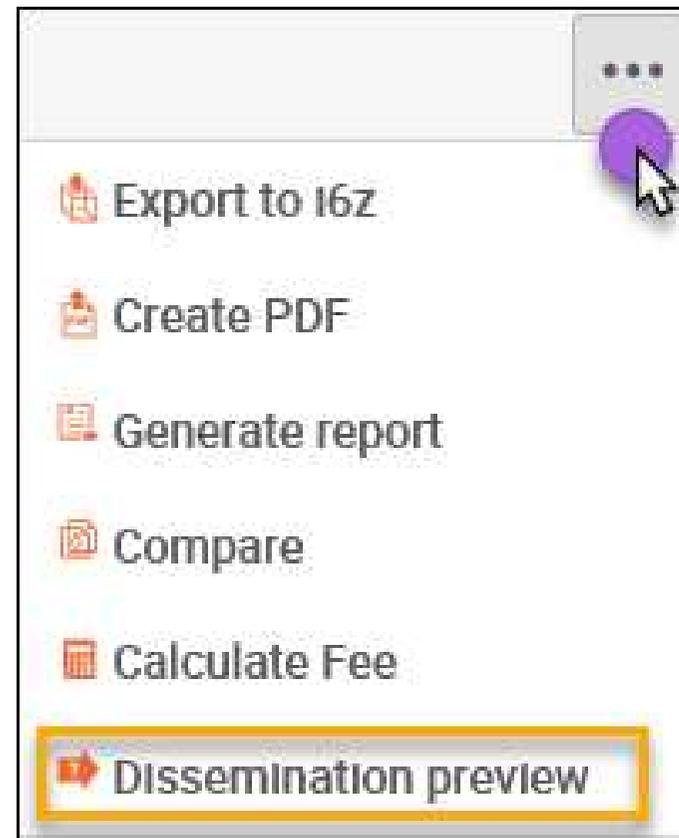
Review the dossier header details

Plug-ins at your service



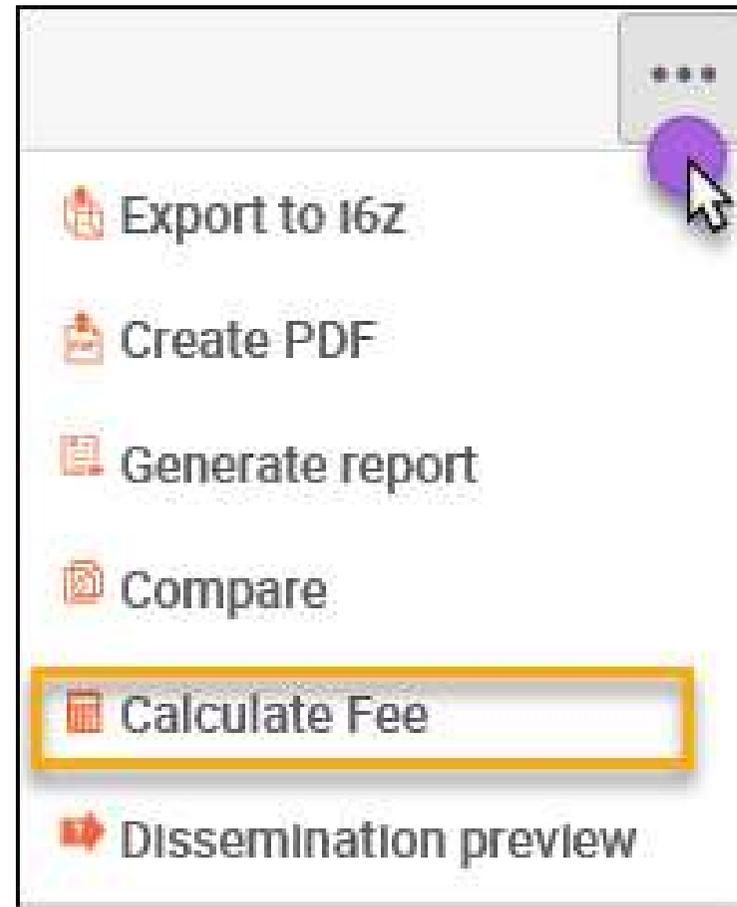
Dissemination preview

- Creates a report of your dossier showing what data get published and what not
- Excel file



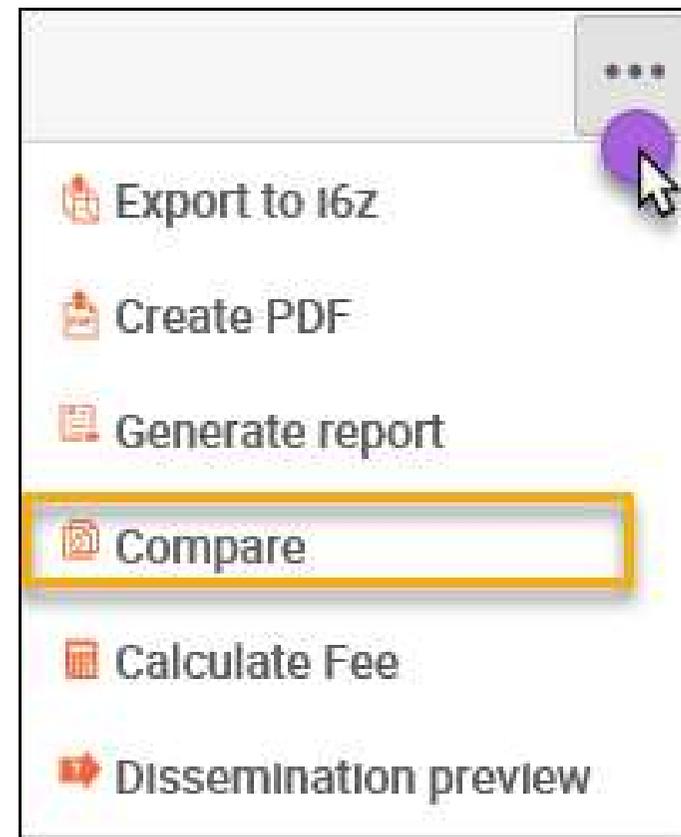
Fee calculator

- Estimates the registration fee
- Shows confidentiality fees
- Note: Make sure your SME status in REACH-IT is correct. It is Large by default.



Comparison tool (1/2)

- Compare your current dossier with a previous one
- What changed and what remained the same
- The report is generated in the HTML format



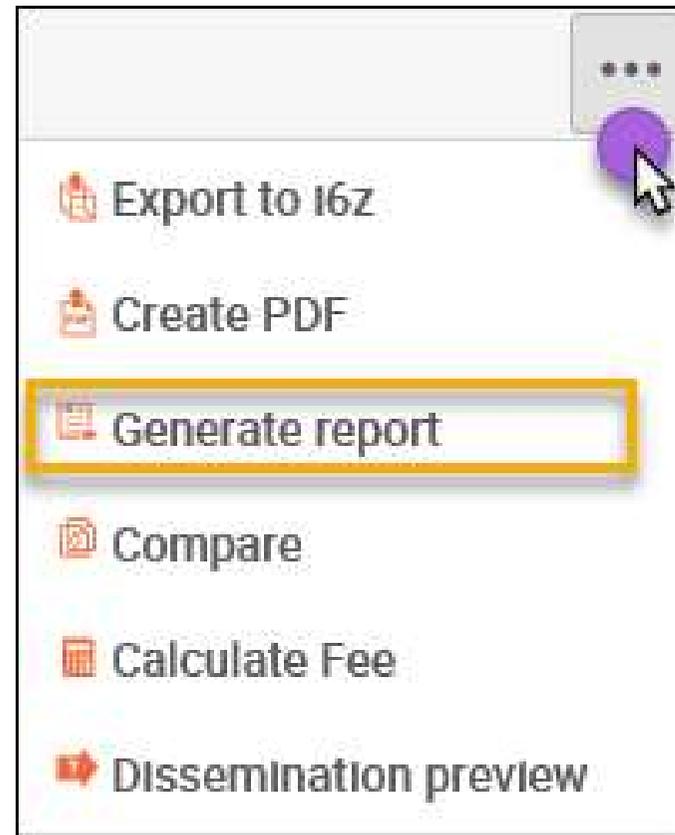
Comparison tool (2/2)

Section Document comparison		
Source	Comparison	Target
1.2 - Composition		
● SubstanceComposition: Fuel oil, residual	 Different	● SubstanceComposition: Fuel oil, residual
1.3 - Identifiers		
● Identifiers: Identifiers	 Identical	● Identifiers: Identifiers
1.4 - Analytical Information		
● AnalyticalInformation: Analytical Information	 Identical	● AnalyticalInformation: Analytical Information

Field	Source	Target
Description <i>i</i> Composition > General Information	Residues which produced in the vacuum distillation of crude oil. Various petroleum refining processes	Guidance on substance ID requires that known constituents above 10%, or constituents driving Classification or PBT/vPvB categorisation are reported. Methods of manufacture of substance

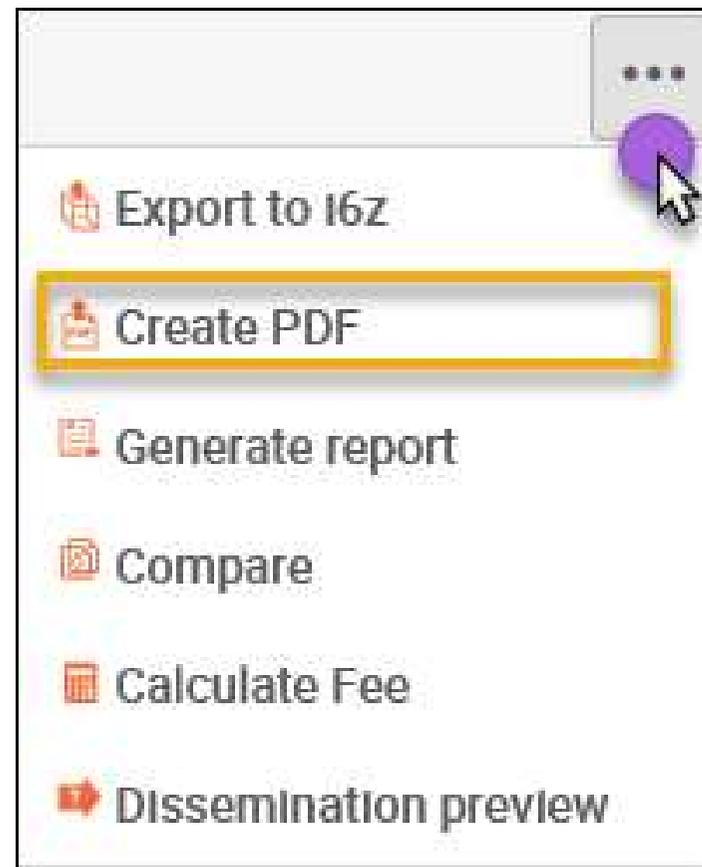
Report generator

- Generates the Chemical safety report (CSR)
- xml, pdf or rtf
- Available both on substance and dossier level



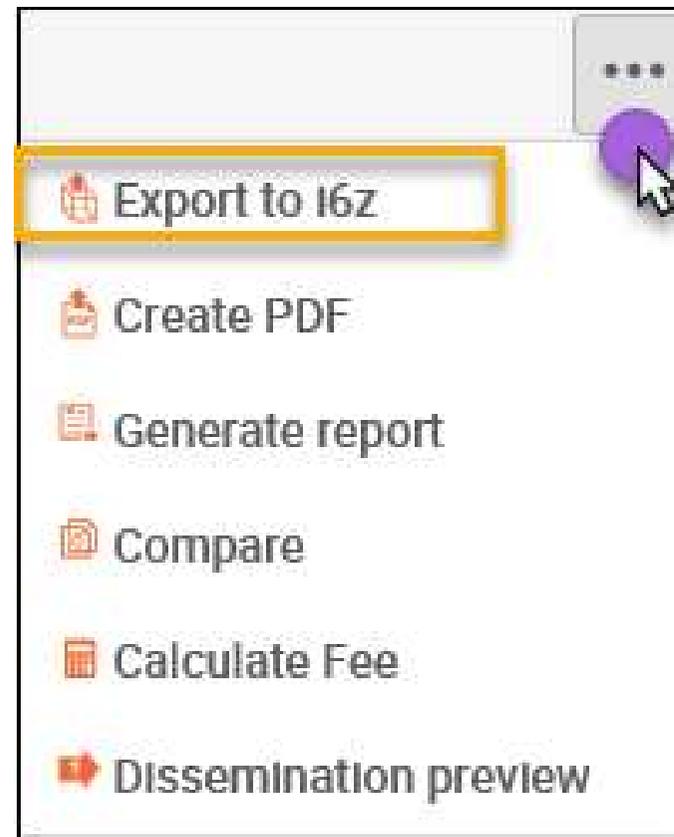
Create pdf

- To create a pdf of your dossier
- For printing
- Available both on substance and dossier level

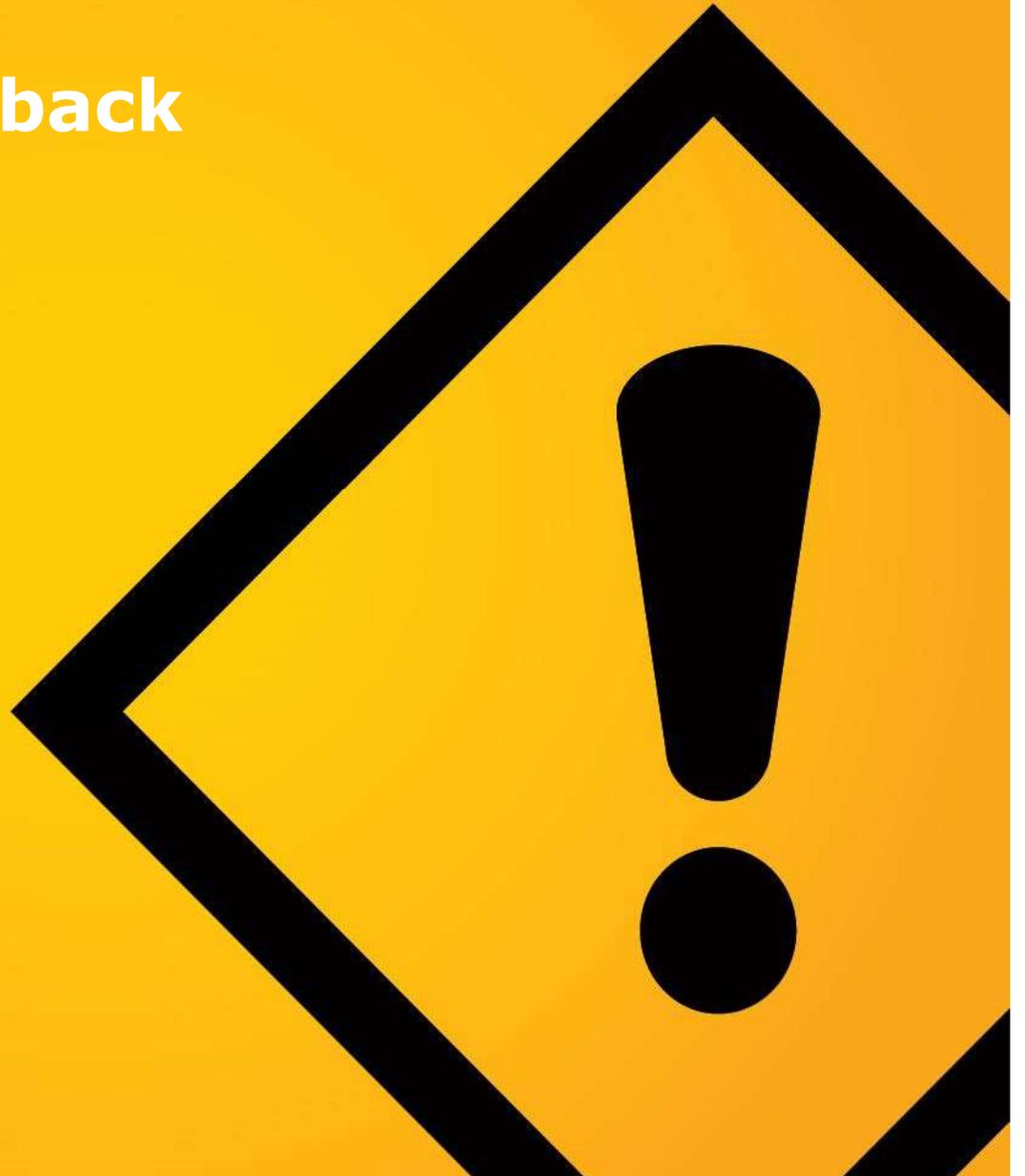


Export file

- To export the substance or the final dossier in .i6z format, e.g., for submission
- Available both on substance and dossier level



Support and feedback



More information on IUCLID web UI

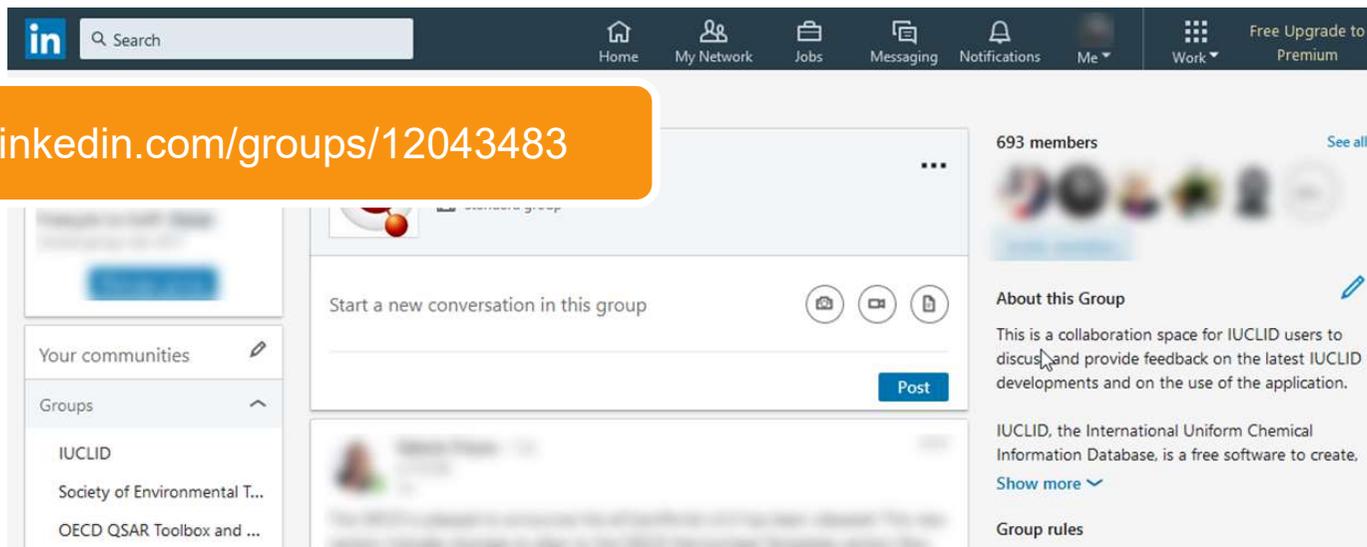
iuclid6.echa.europa.eu

Videos and webinars

IUCLID video tutorials

Videotutorials on some key features of IUCLID have been published on the ECHA YouTube channel: [go to the YouTube playlist](#) or directly access a specific video from the links below.

- Specific videos relevant to the new IUCLID web-based user interface
 - How to open the web UI in IUCLID 6.3
 - Getting to know: IUCLID 6.3 web user interface
 - IUCLID 6.3 web user interface: key functionalities
 - How to use a browser to bookmark substances and documents
 - How to create, edit and delete documents in IUCLID



The screenshot shows the LinkedIn interface for the IUCLID group. At the top, there is a navigation bar with icons for Home, My Network, Jobs, Messaging, Notifications, and Me. A search bar is also present. Below the navigation bar, the group name "IUCLID" is visible, along with a "693 members" count and a "See all" link. The main content area features a "Start a new conversation in this group" prompt with icons for video, voice, and text, and a "Post" button. To the right, there is an "About this Group" section with a description: "This is a collaboration space for IUCLID users to discuss and provide feedback on the latest IUCLID developments and on the use of the application." Below this, it states "IUCLID, the International Uniform Chemical Information Database, is a free software to create." and includes a "Show more" link. At the bottom right, there is a "Group rules" link.

<https://www.linkedin.com/groups/12043483>

Feedback

- Your feedback on the new IUCLID web user interface will help us to successfully complete the switch from the classic user interface to the web user interface
- Please share your comments on the web UI via the ECHA contact form at <https://echa.europa.eu/contact>



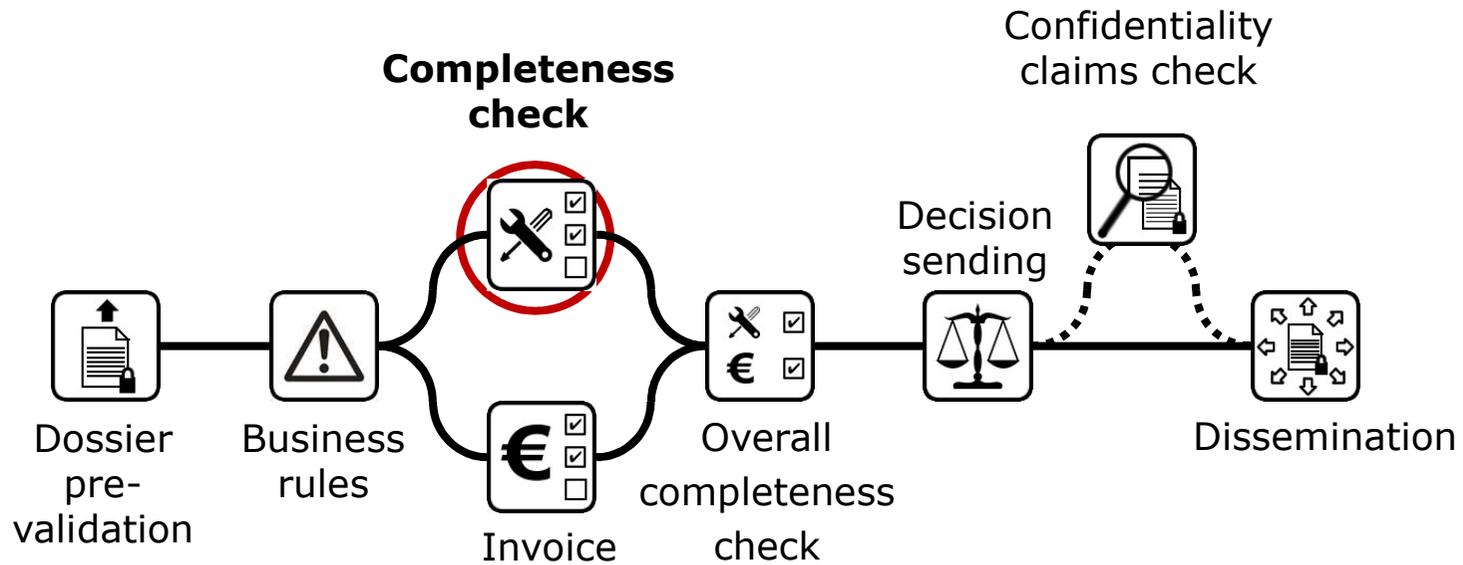
Completeness check

Manual verification

12 June 2019

Margot Mägi
Data Availability Unit
ECHA

Completeness check (1/3)



Completeness check (2/3)

- The completeness check ensures that all the required elements are in the registration dossier as per Article 20(2) of REACH Regulation
- It is performed on each registration dossier submitted to ECHA – both initial and update submissions

Completeness check (3/3)

- 2010 – the REACH information requirements were converted into automated completeness check rules.
- 21 June 2016 – enhanced completeness check enters into force: revised automated rules and additional manual checks performed by ECHA staff.
 - Not displayed by the Validation assistant
 - To ensure that registrants who deviate from standard requirements provide a justification that is relevant within the REACH context.

Completeness check outcome (1/3)

Completeness check passes:



- Message from ECHA in REACH-IT
- If the payment (when relevant) is received on time, your submission is complete and a positive decision is sent to you via REACH-IT
 - **Initial submission:** registration number assigned.
 - **Update of existing registration:** ECHA will accept the updated information in the database.

Completeness check outcome (2/3)

Failure of completeness check 1st time:



- Letter in the REACH-IT task box.
- Both initial submission and update of existing registration:
 - Only one possibility to submit a complete dossier
 - Deadline specified in the letter
 - Failures listed in Annex 1

Completeness check outcome (3/3)

Failure of completeness check 2nd time: **XX**

- Negative decision in the REACH-IT task box, informing that submission is rejected.

Initial submission:

- Registration number not granted
- Fee is not refunded (if invoice was issued)

Update of existing registration:

- The updated information is not accepted into the ECHA database
- You keep your registration number
- After rejection you can submit a new dossier for the substance

Areas of manual checks

- **Substance identification** (IUPAC name, composition, manufacturing process description of UVCB substances, analytical information)
- Justification for **waiving** of standard information requirements
- **Testing proposals** on vertebrate animals (presence of considerations for adaptation possibilities)
- Justification for waiving of **Chemical safety report**
- **Opt-out** justifications

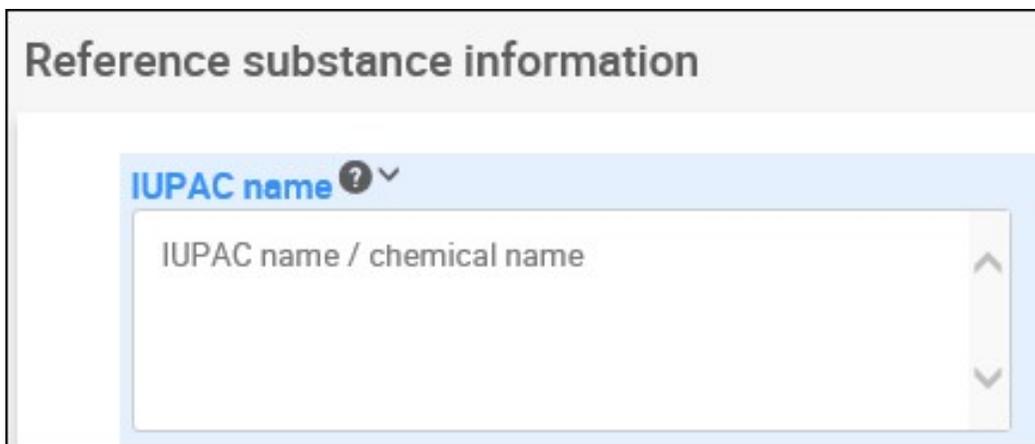
Substance identification

Areas of manual
Completeness checks



IUPAC name of the registered substance

- IUPAC name must always be provided in the 'IUPAC name' field in the IUCLID section 1.1 Reference substance.
- If the substance has no official IUPAC name, the chemical name must be provided in the IUPAC name field.



The screenshot shows a web form titled "Reference substance information". Within this form, there is a section for "IUPAC name" which includes a question mark icon and a dropdown arrow. Below this is a text input field containing the placeholder text "IUPAC name / chemical name".

Number of constituents

- For a mono-constituent substance, each reported composition is expected to contain only one constituent.
- For a multi-constituent substance, each reported composition is expected to contain more than one constituent.

Reporting of multi-constituent composition in a mono-constituent dossier, and vice versa, is required in specific cases, and must be justified under '[Justification for deviations](#)'.

Composition of mono-constituent substances (80-20% rule)

- For a mono-constituent substance:
 - the main constituent is expected to be present in each reported composition as a minimum at 80% (concentration range and/or typical concentration).
 - impurities are expected to be present in each reported composition as a maximum at 20%

If the registered substance deviates from this rule, the scientifically substantiated reason must be given in the '[Justification for deviations](#)' field.

Composition of multi-constituent substances (80-10% rule)

- For a multi-constituent substance:
 - the main constituents are expected to be present in each reported composition as a maximum at 80% (concentration range and/or typical concentration).
 - impurities are expected to be present in each reported composition as a maximum at 10%

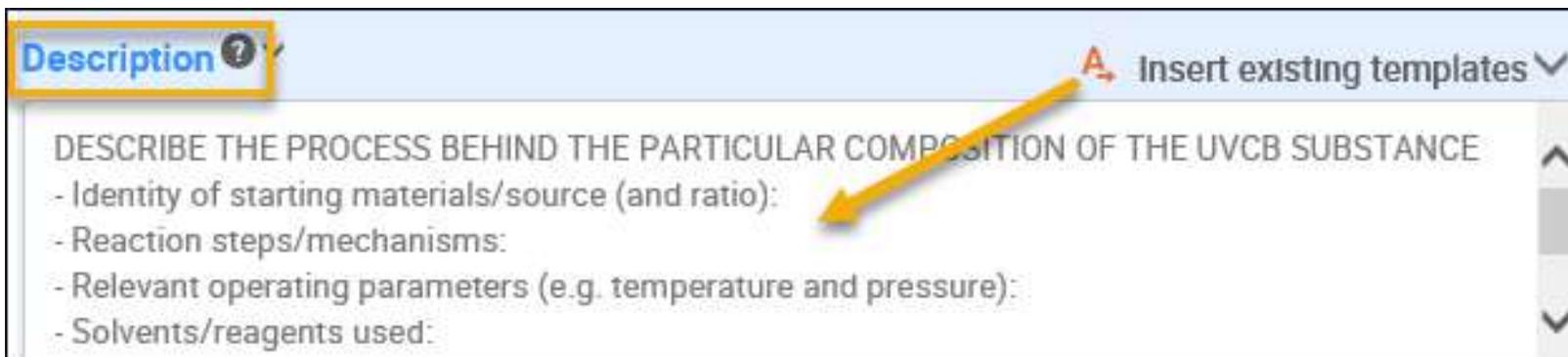
If the registered substance deviates from this rule, the scientifically substantiated reason must be given in the '[Justification for deviations](#)' field.

Composition of a UVCB substance

- The constituents for each reported composition of a UVCB substance must be provided in IUCLID section 1.2. under '**Constituents**':
 - All individual constituents present at >10%, or relevant for C&L and/or PBT assessment must be reported separately.
 - Other constituents should be identified as far as possible, as separate constituents or as groups of generic constituents.
 - In exceptional cases, if not possible to report any (groups of) constituents separately, provide a scientifically fully substantiated justification under '**Justification for deviations**'.

Manufacturing process description of UVCB substance

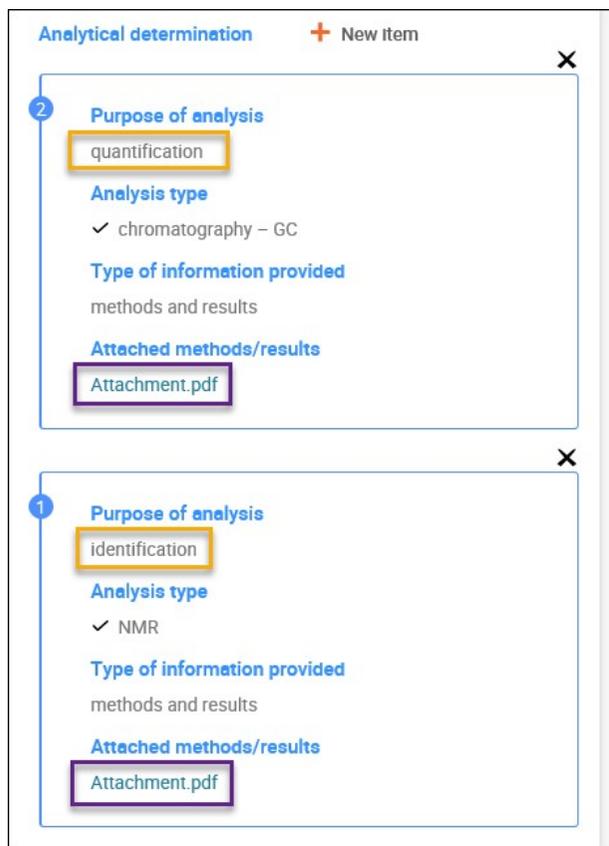
- A description of the source used and the process applied must be included in the 'Description' field in IUCLID section 1.2.
- Use the free text template of the IUCLID field marked with "A" to help you report relevant information.



The screenshot shows a software interface for the 'Description' field. The field title 'Description' is highlighted with a yellow box. To the right, there is a button labeled 'A Insert existing templates' with a dropdown arrow. Below the title, a template text is displayed: 'DESCRIBE THE PROCESS BEHIND THE PARTICULAR COMPOSITION OF THE UVCB SUBSTANCE'. A yellow arrow points from the 'A' in the button to the first line of the template. The template includes a list of bullet points: '- Identity of starting materials/source (and ratio):', '- Reaction steps/mechanisms:', '- Relevant operating parameters (e.g. temperature and pressure):', and '- Solvents/reagents used:'. A vertical scrollbar is visible on the right side of the text area.

Analytical information

- The required analytical reports for identification and quantification must be attached in IUCLID section 1.4.



Analytical determination + New item

2 **Purpose of analysis**
quantification

Analysis type
 chromatography - GC

Type of information provided
methods and results

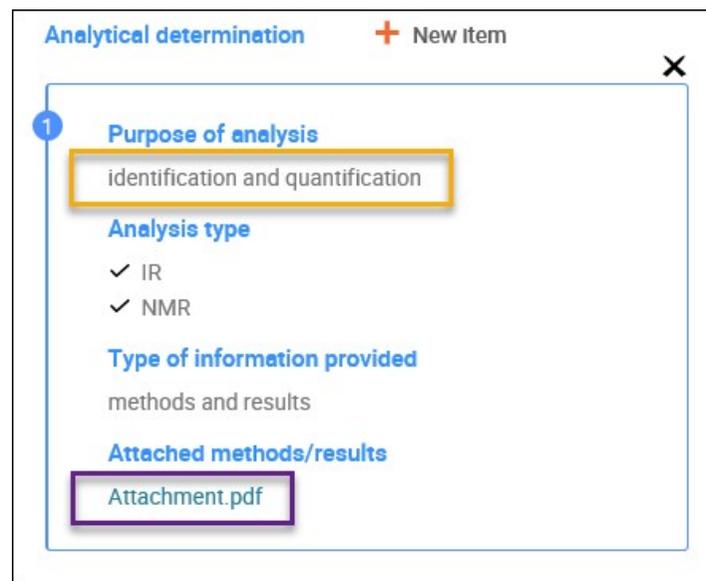
Attached methods/results
Attachment.pdf

1 **Purpose of analysis**
identification

Analysis type
 NMR

Type of information provided
methods and results

Attached methods/results
Attachment.pdf



Analytical determination + New item

1 **Purpose of analysis**
identification and quantification

Analysis type
 IR
 NMR

Type of information provided
methods and results

Attached methods/results
Attachment.pdf

Data waiving

Areas of manual
Completeness checks

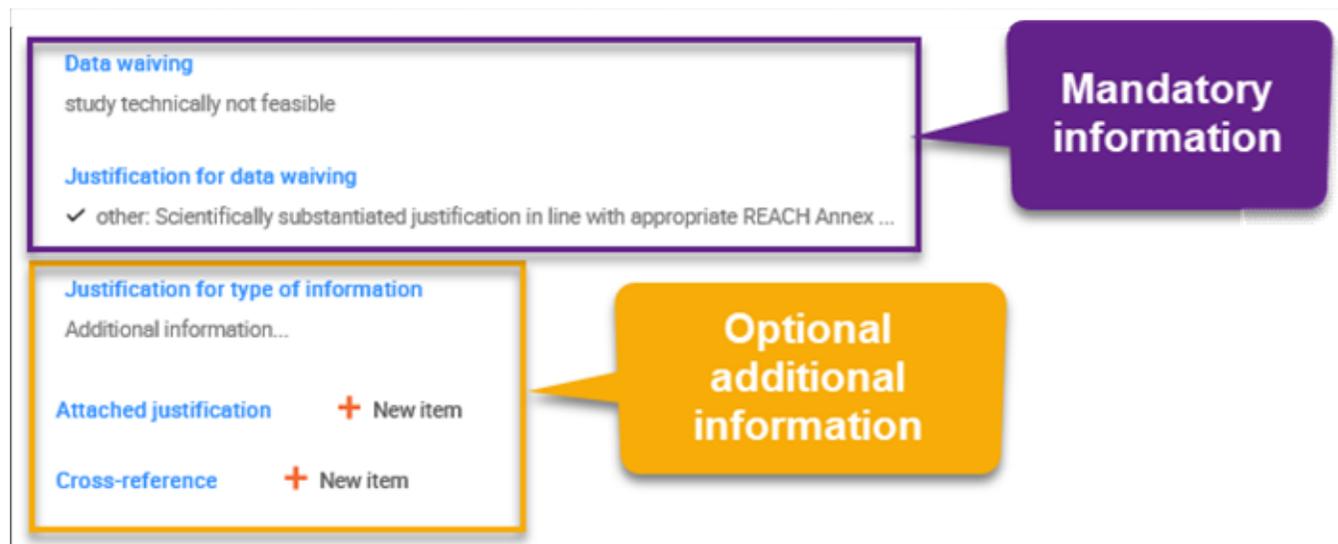


Justification for data waiving (1/4)

- A data waiving justification must be in accordance with Column 2 of REACH Annexes VII – X, or Annex XI sections 2 and 3.
- Enter the justification in the field '**Justification for data waiving**'.
 - Picklist options available in IUCLID, consider using if option(s) apply to your particular case.
 - If picklist options do not apply, choose 'other' and provide a scientifically substantiated justification in line with appropriate REACH Annex

Justification for data waiving (2/4)

- More information can be provided in the field 'Justification for type of information' and 'Attached justification'.
- Reference to information elsewhere in the dossier can be provided using the 'Cross-reference' field.



Justification for data waiving (3/4)

- Be precise on what you base your justification
- Give a scientifically robust explanation, in line with Column 2 of REACH, for why the test does not need to be conducted; do not just refer to your opinion or experience
- It is not enough to say that the substance is a UVCB; also UVCB substances must be tested. Also naturally occurring substances must be tested

Justification for data waiving (4/4)

Examples of **incomplete**/**complete** justifications for data waiving:

Auto-flammability (REACH Annex VII, 7.12)

“It is known from experience on handling the substance that it does not self ignite.”

“According to REACH Annex VII section 7.12 column 2 the test on self-ignition does not need to be conducted as the substance is a liquid with a flash point above 200°C.”

Explosiveness (REACH Annex VII, 7.11)

“The substance is not explosive.”

“There are no chemical groups associated with explosive properties in the molecule. For further details, see the expert report in the field ‘Attached justification’.”

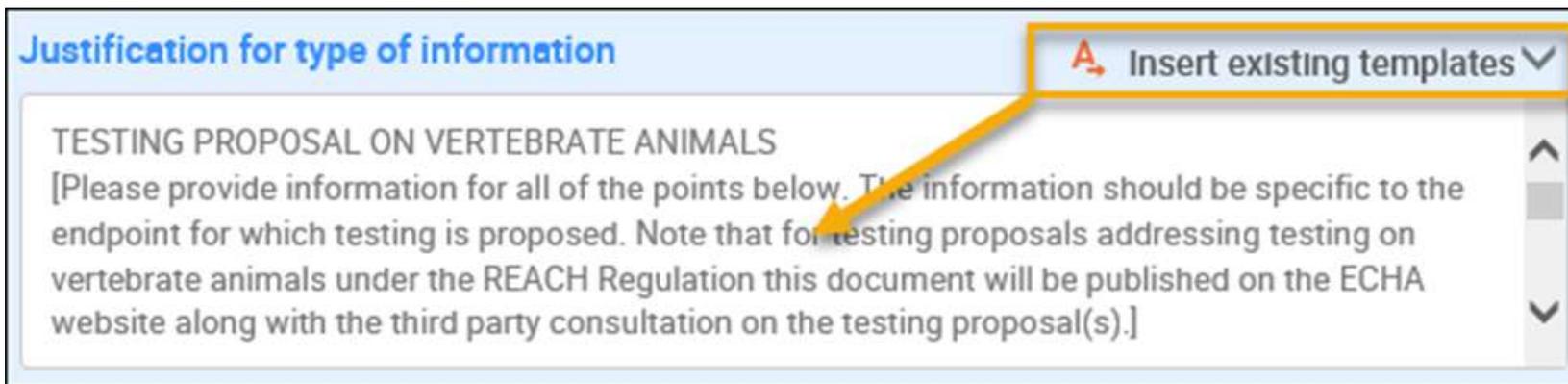
Testing proposals

Areas of manual
completeness checks



Testing proposals on vertebrate animals

- Considerations of alternatives must be provided in the field 'Justification for type of information' for each proposed vertebrate study
- Use the free text template marked with "A" when documenting your considerations



Justification for type of information

A Insert existing templates ▾

TESTING PROPOSAL ON VERTEBRATE ANIMALS
[Please provide information for all of the points below. The information should be specific to the endpoint for which testing is proposed. Note that for testing proposals addressing testing on vertebrate animals under the REACH Regulation this document will be published on the ECHA website along with the third party consultation on the testing proposal(s).]

Chemical safety report

Areas of manual
completeness checks



Chemical safety report (CSR)

- A CSR is required for substances registered >10 T
 - If a CSR is not attached, a justification why a CSR is not required must be included in the section 13 field '[Further information on the attached file](#)' or the field 'Discussion'.
 - Article 14(2) of REACH sets out an exhaustive list of reasons why a chemical safety assessment does not need to be carried out, and a CSR submitted in the dossier.
 - Explain clearly how your substance meets the Article 14(2) criteria – general reference is not enough.

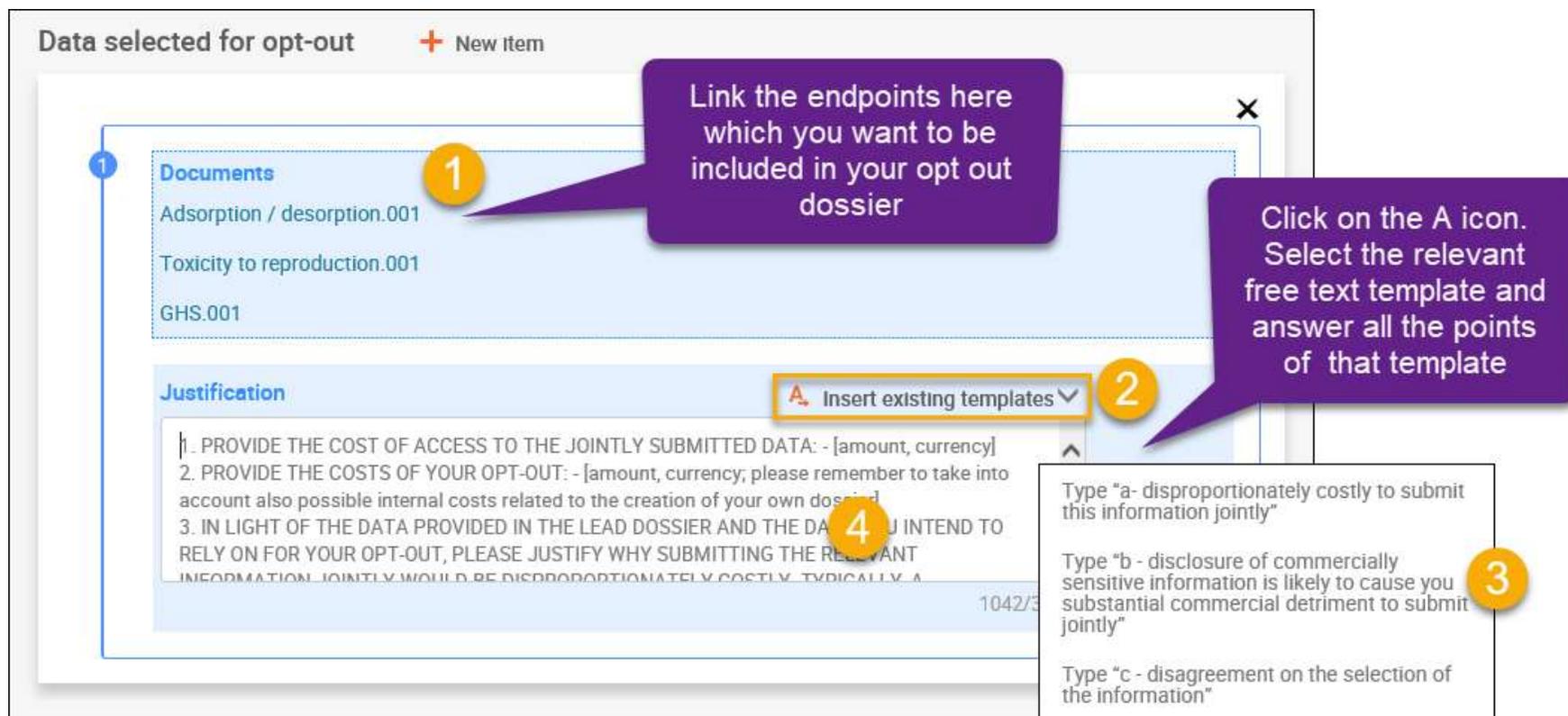
Opt-out justification

Areas of manual
completeness checks



- There are three different reasons under Article 11(3) or 19(2) under which a company can undertake an opt-out:
 - Disagreement on the costs of submitting jointly (template 'a')
 - Disclosure of commercially sensitive business information (template 'b')
 - Disagreement with the existing registrants on the selection of data (template 'c')
- To facilitate the drafting of the justification there are free text templates in IUCLID section 14 (a, b and c)
- All points of at least one template must be fully answered

Opt-out justification (2/2)



The screenshot shows the 'Data selected for opt-out' interface. At the top, it says 'Data selected for opt-out' and '+ New Item'. Below this, there are two main sections: 'Documents' and 'Justification'.

Documents: A list of documents is shown, including 'Adsorption / desorption.001', 'Toxicity to reproduction.001', and 'GHS.001'. A callout box with a '1' in a yellow circle points to this list, containing the text: 'Link the endpoints here which you want to be included in your opt out dossier'.

Justification: A text area for justification is shown. A dropdown menu labeled 'A. Insert existing templates' is highlighted with a callout box with a '2' in a yellow circle, containing the text: 'Click on the A icon. Select the relevant free text template and answer all the points of that template'. Below the dropdown, a list of template options is visible, with a callout box with a '3' in a yellow circle pointing to the first option: 'Type "a- disproportionately costly to submit this information jointly"'. A callout box with a '4' in a yellow circle points to the text area, containing the text: 'Provide the cost of access to the jointly submitted data: - [amount, currency]'. The text area also contains other numbered points: '2. PROVIDE THE COSTS OF YOUR OPT-OUT: - [amount, currency; please remember to take into account also possible internal costs related to the creation of your own dossier]' and '3. IN LIGHT OF THE DATA PROVIDED IN THE LEAD DOSSIER AND THE DATA YOU INTEND TO RELY ON FOR YOUR OPT-OUT, PLEASE JUSTIFY WHY SUBMITTING THE RELEVANT INFORMATION JOINTLY WOULD BE DISPROPORTIONATELY COSTLY. TYPICALLY A'.

Key to completeness



Key points for completeness (1/3)

- Be clear and transparent
- Use the correct field to provide the summary of the main points of the justification
- A reference alone to another field is not enough
- Use standard phrases and picklist values where relevant
- Every 'other:' has to be followed by free text
- Use free text templates to know what is expected and answer all the points

Key points for completeness (2/3)

- If your previous dossier was submitted using IUCLID 5 you may need to revise the data before submitting it in IUCLID 6 format.
- If your submission failed Completeness check read through the letter sent to you. Mind the deadline given.
- To avoid introducing new completeness check failures it is not advisable to update any other parts of the dossier than those listed in Annex 1 of the letter

Key points for completeness (3/3)

- Run the Validation assistant
- Monitor your REACH-IT tasks and messages regularly
- Have a relevant contact person assigned to your submission so we can reach her/him by phone and e-mail
- If you need help, contact us via the contact form:
<http://echa.europa.eu/contact>

Support material



Manual “How to prepare a registration and PPORD dossier”:

<http://echa.europa.eu/manuals>

Further information on the areas of manual verification:

https://echa.europa.eu/documents/10162/13652/manual_completeness_check_en.pdf

Frequently asked questions on the completeness check and other topics:

<https://echa.europa.eu/support/qas-support/browse>

Guidance for identification and naming of substances under REACH and CLP:

<http://echa.europa.eu/guidance-documents/guidance-on-reach>

Contact ECHA via the contact form:

<https://echa.europa.eu/contact>

Questions?

? & A

Thank you!

margot.magi@echa.europa.eu