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

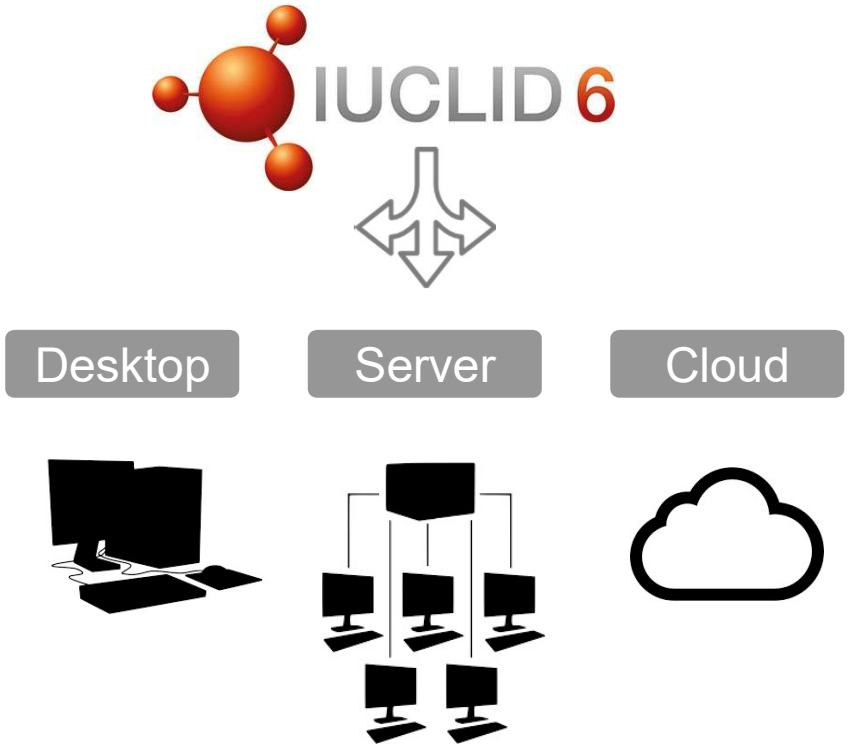
12 June 2019

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

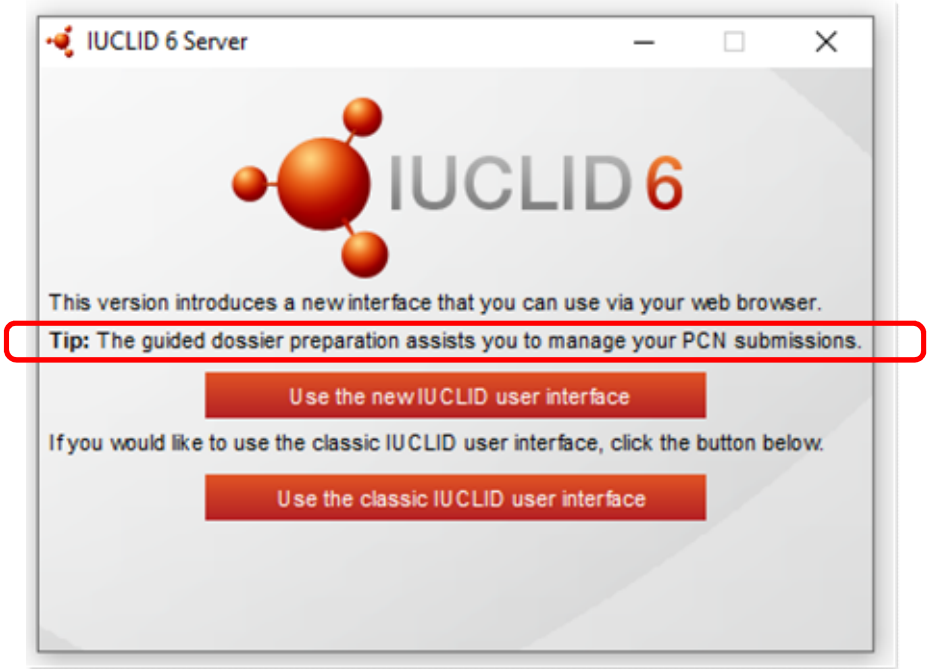


IUCLID Web user interface

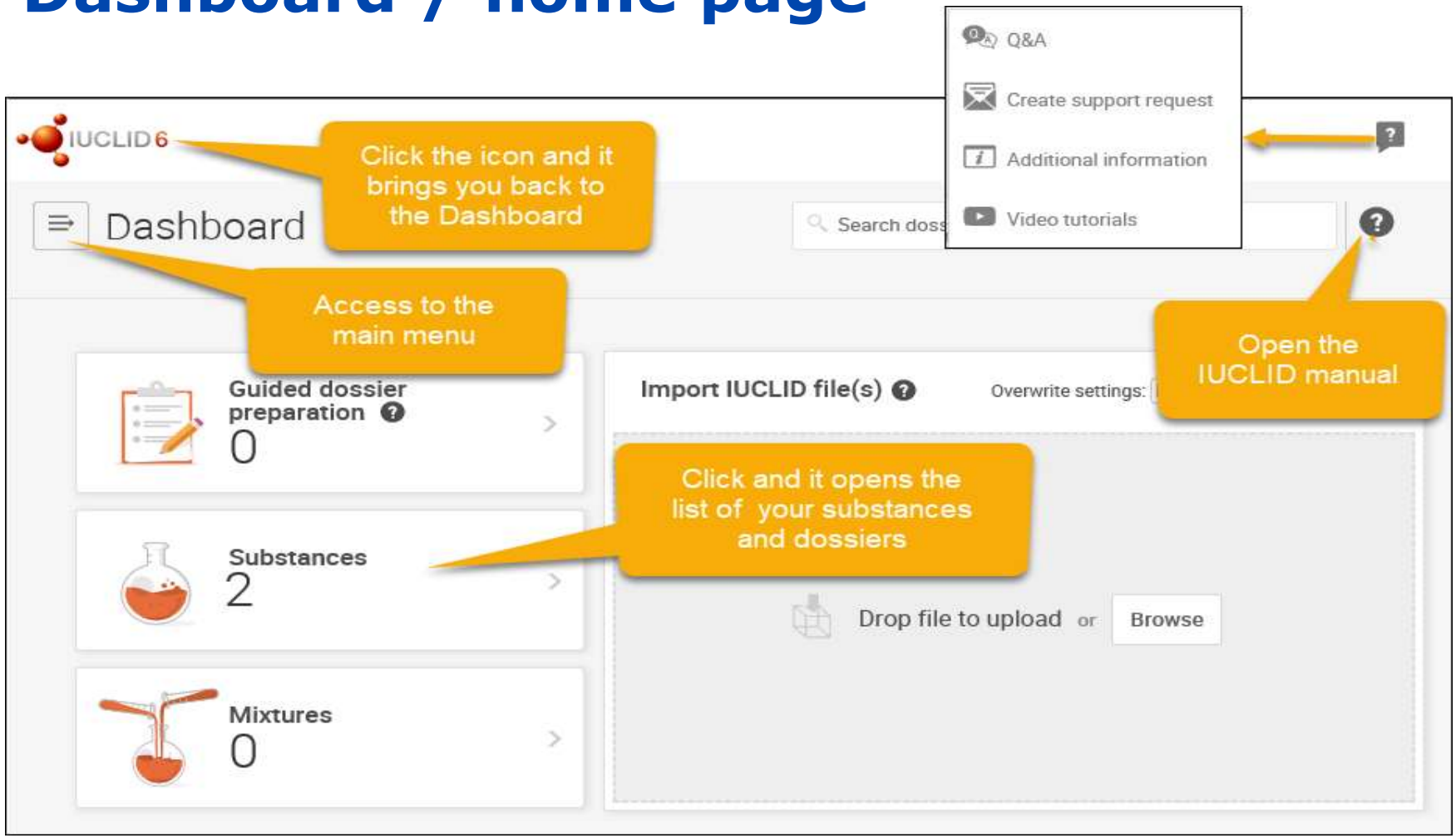
- Available since November 2018, IUCLID version 6.3
- Available for server and desktop IUCLID
- Look and feel the same as in IUCLID Cloud

What is the pre-launch screen

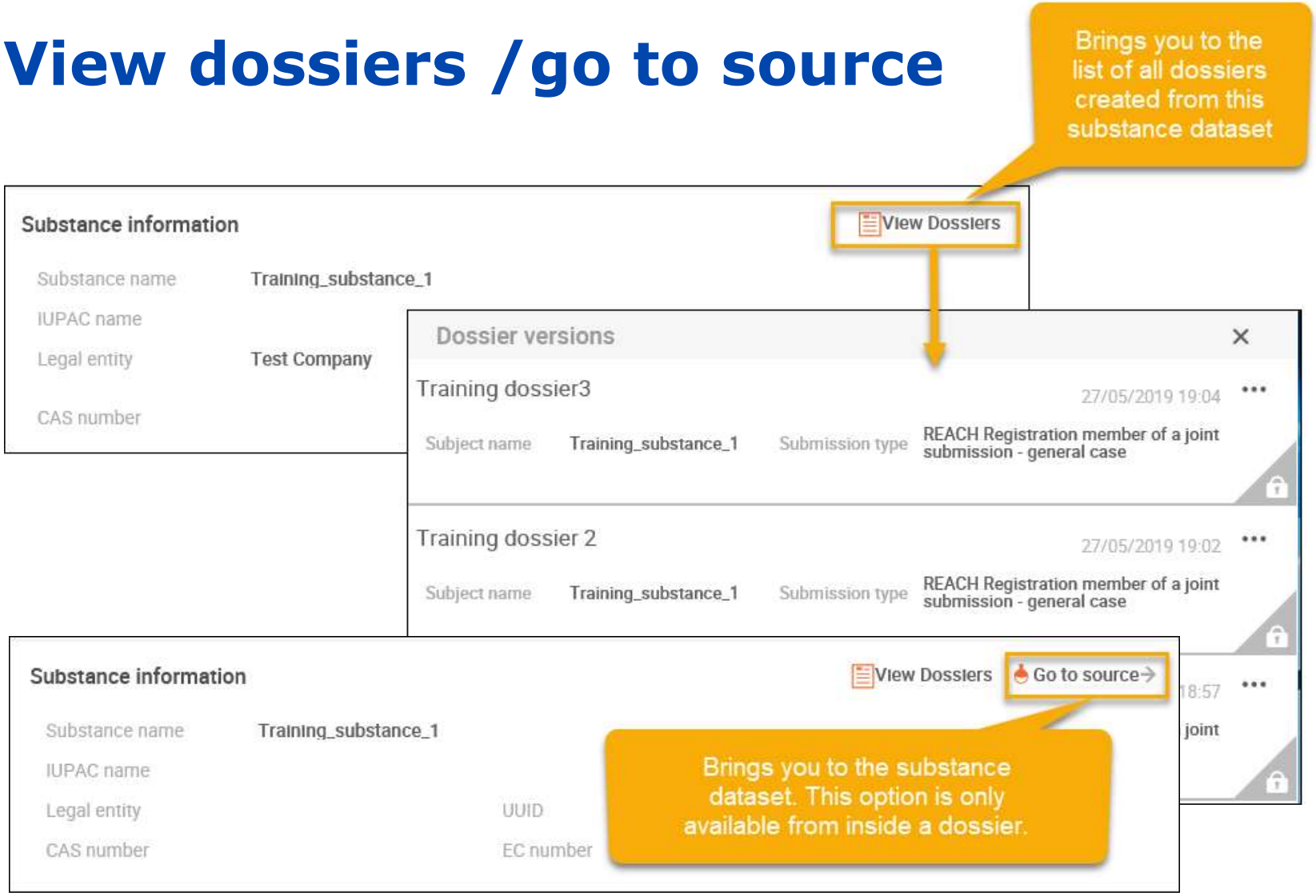
- Swift between the classic and the web interface
- If closed, it triggers exiting IUCLID
- A new tip is displayed with every launch



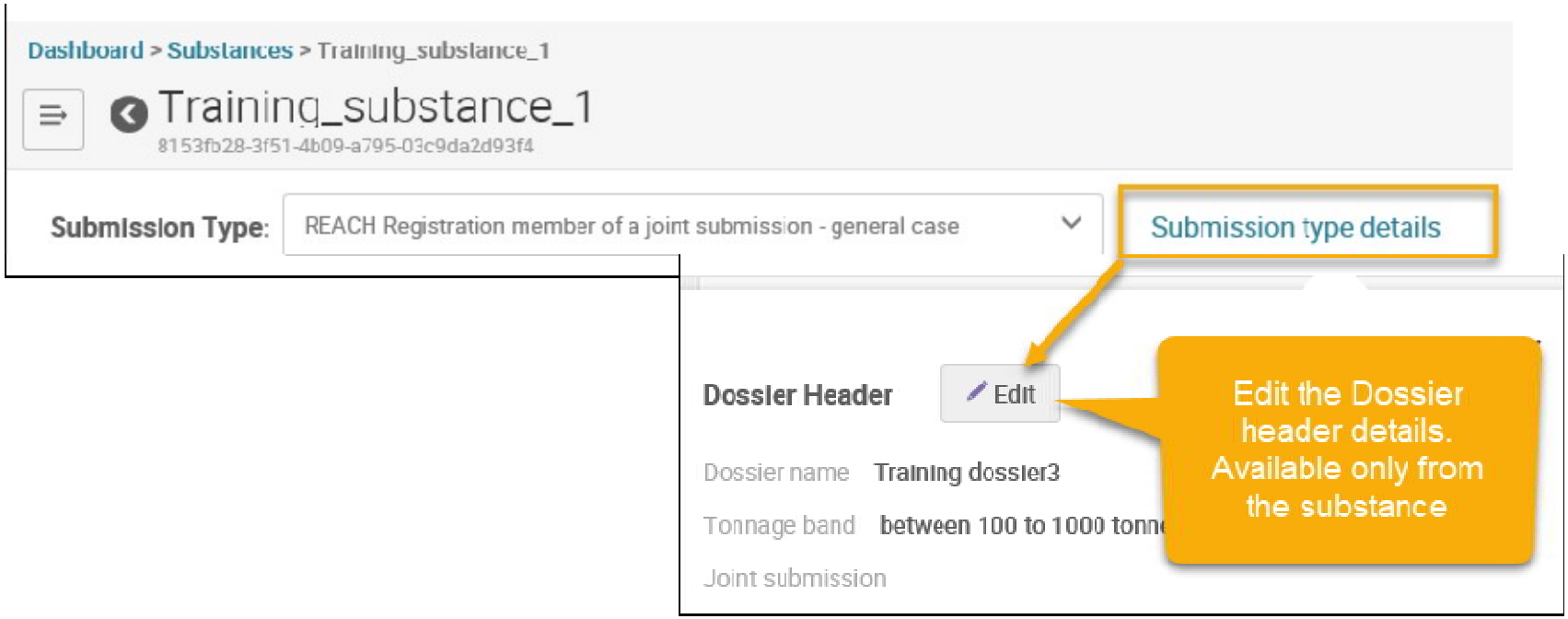
Dashboard / home page



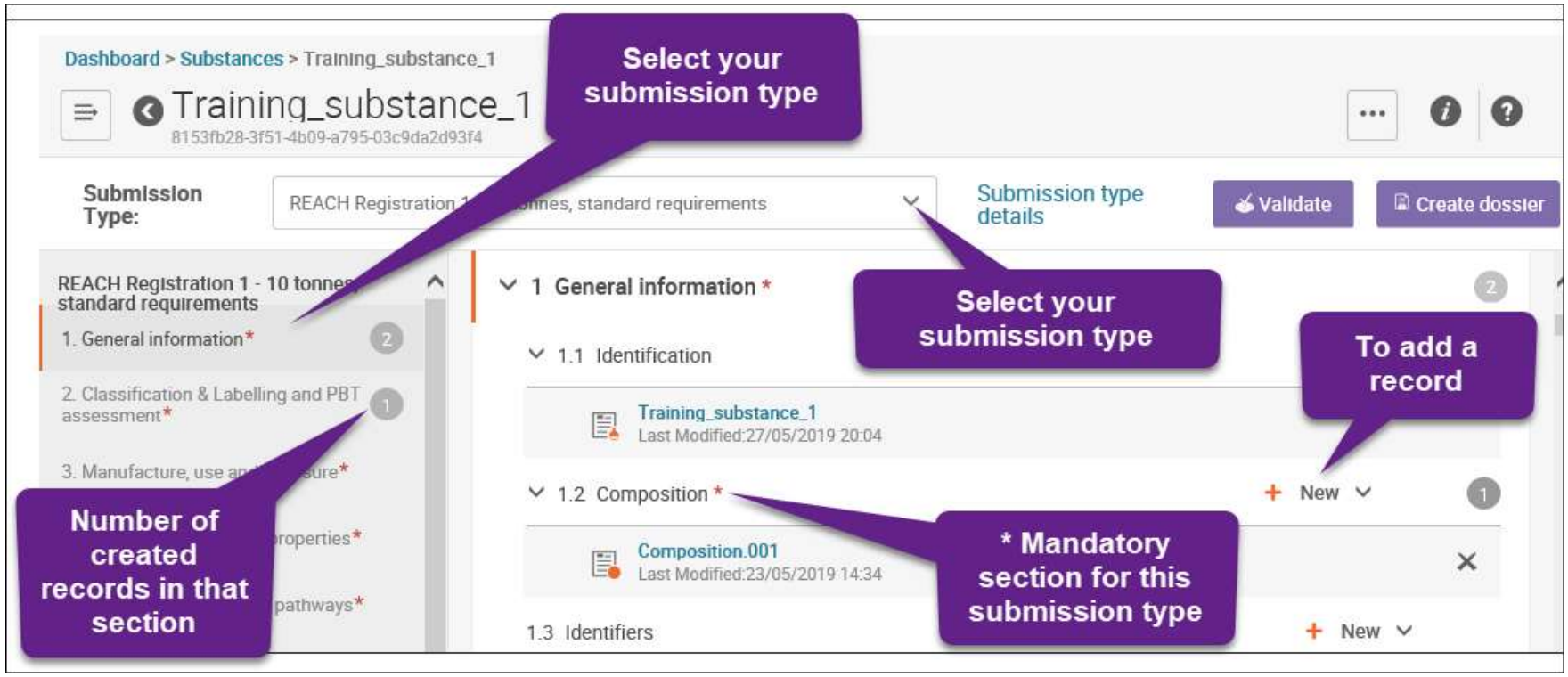
View dossiers /go to source



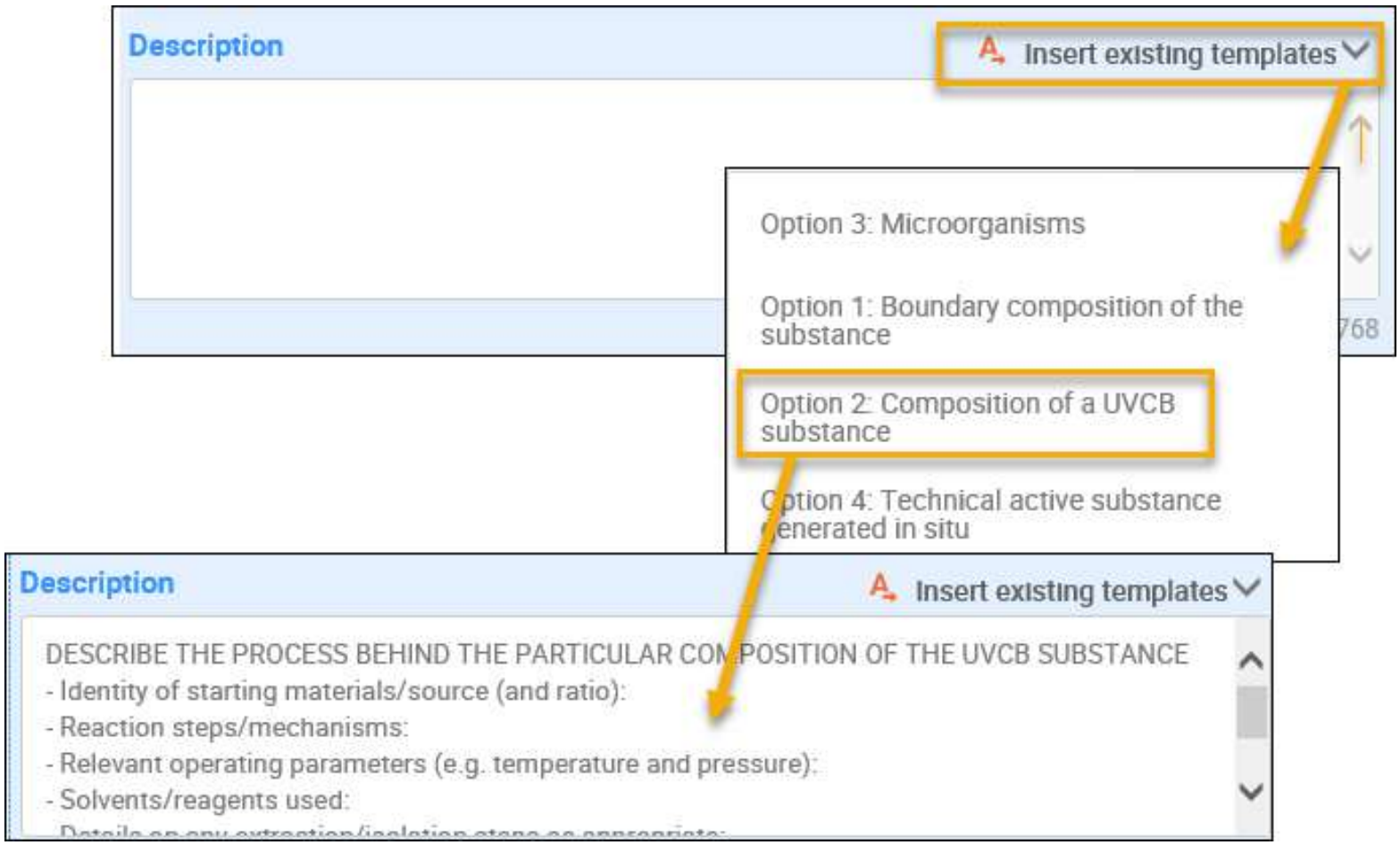
Dossier header



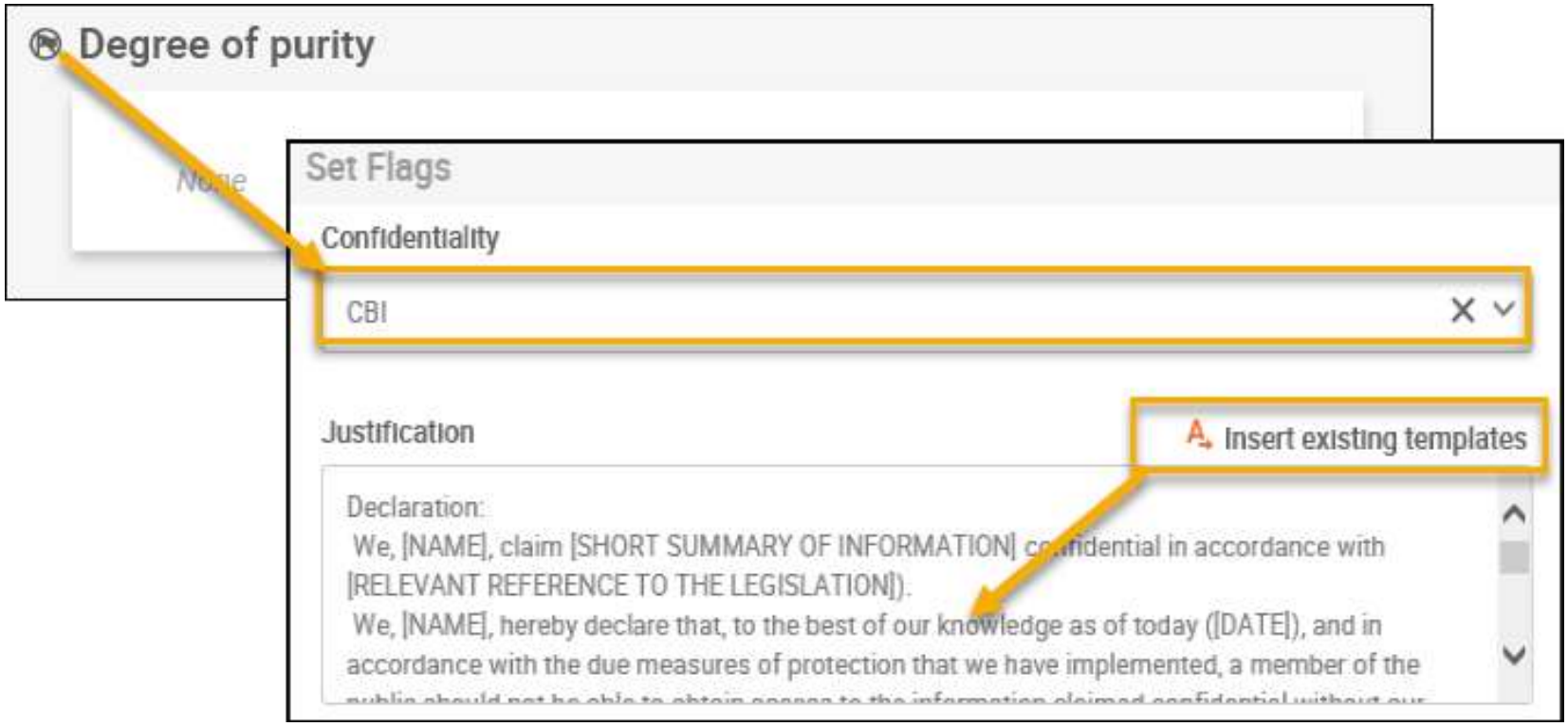
Section tree



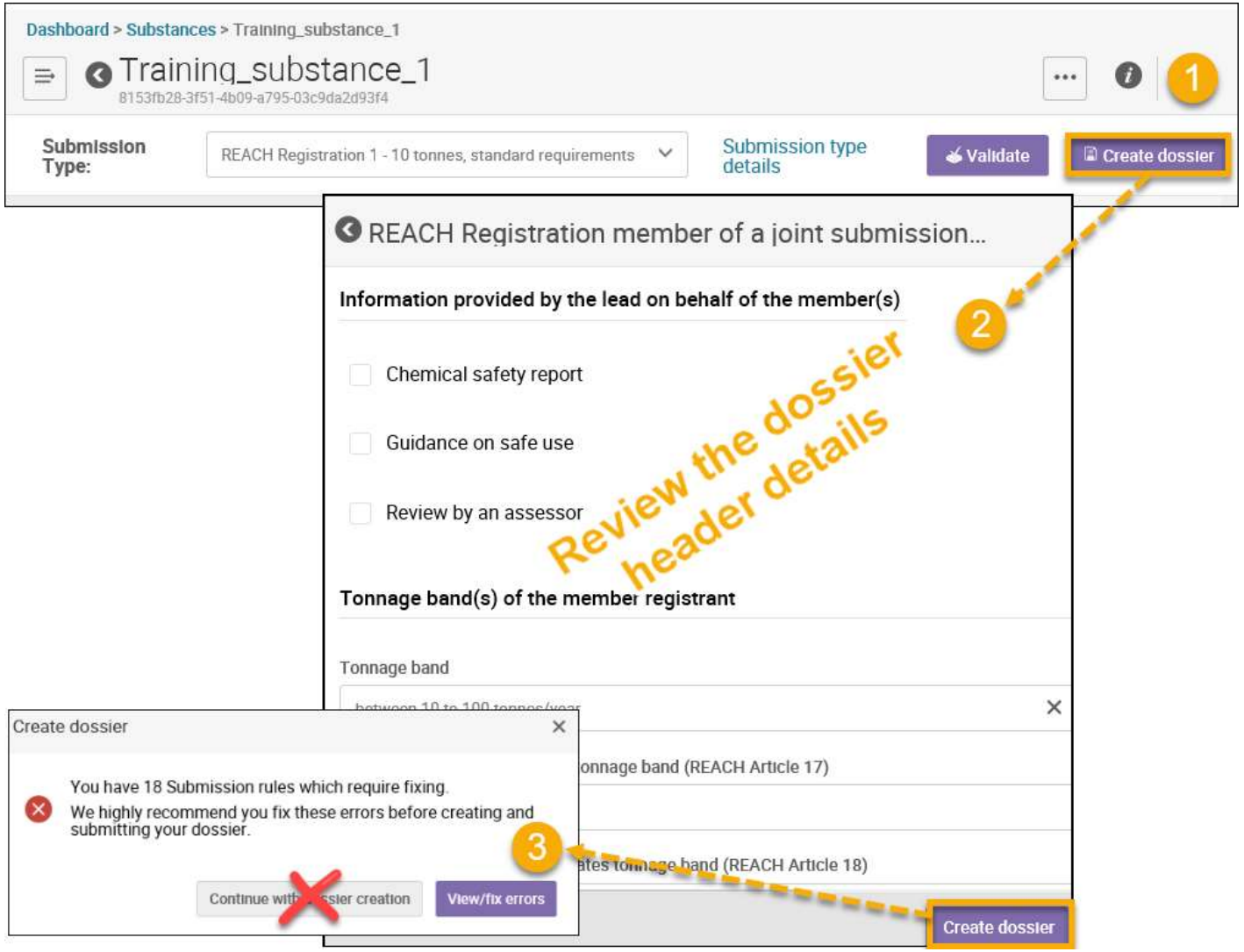
Free text template



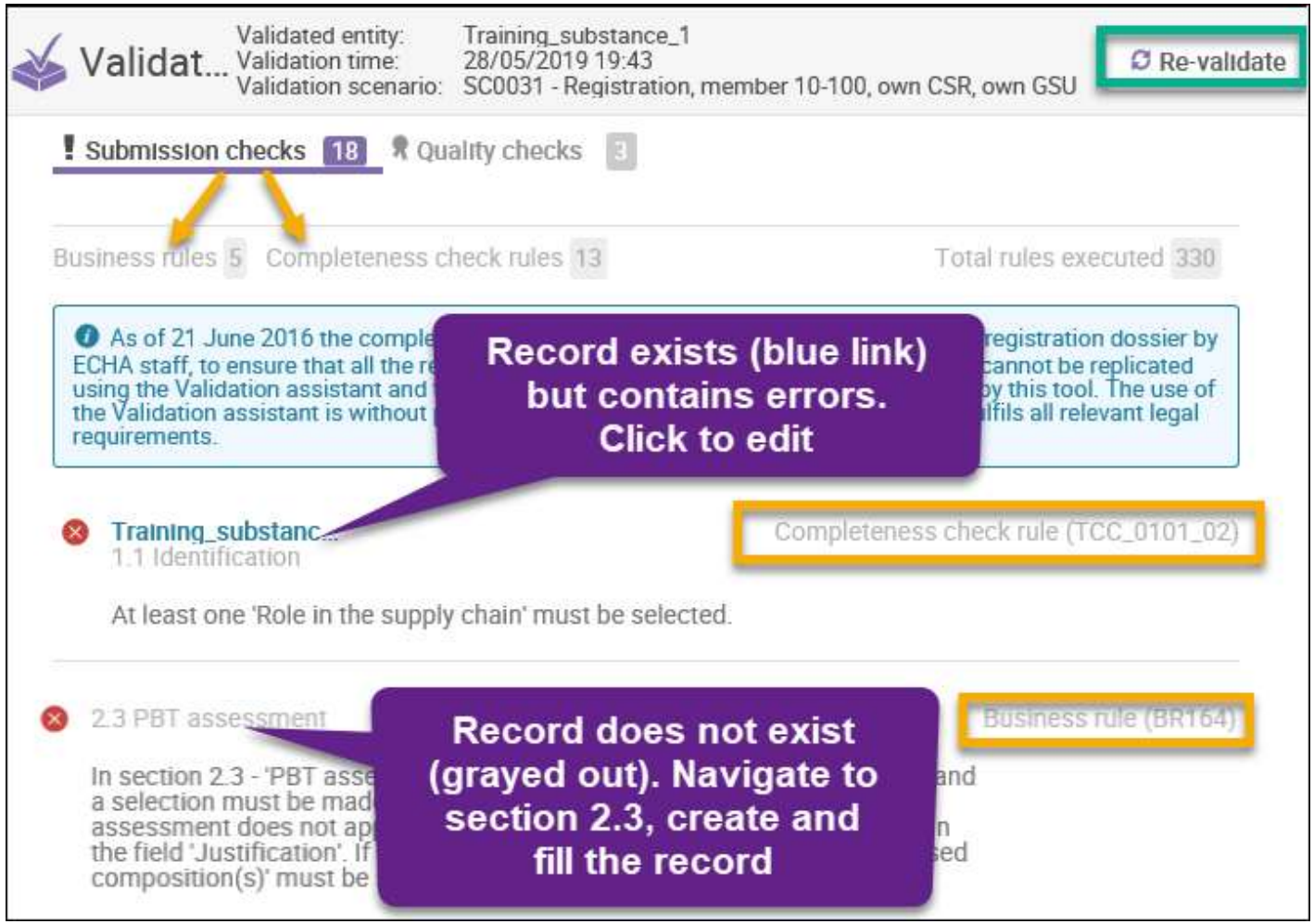
Flag


Degree of purity
None
Set Flags
Confidentiality
CBI
Justification
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

Dossier creation



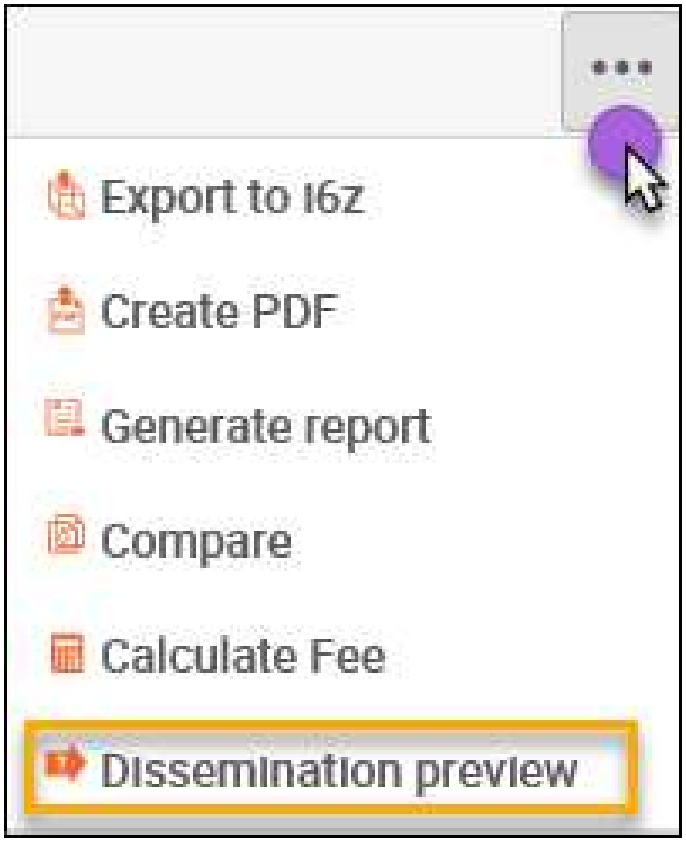
Validation assistant



Plug-ins at your service

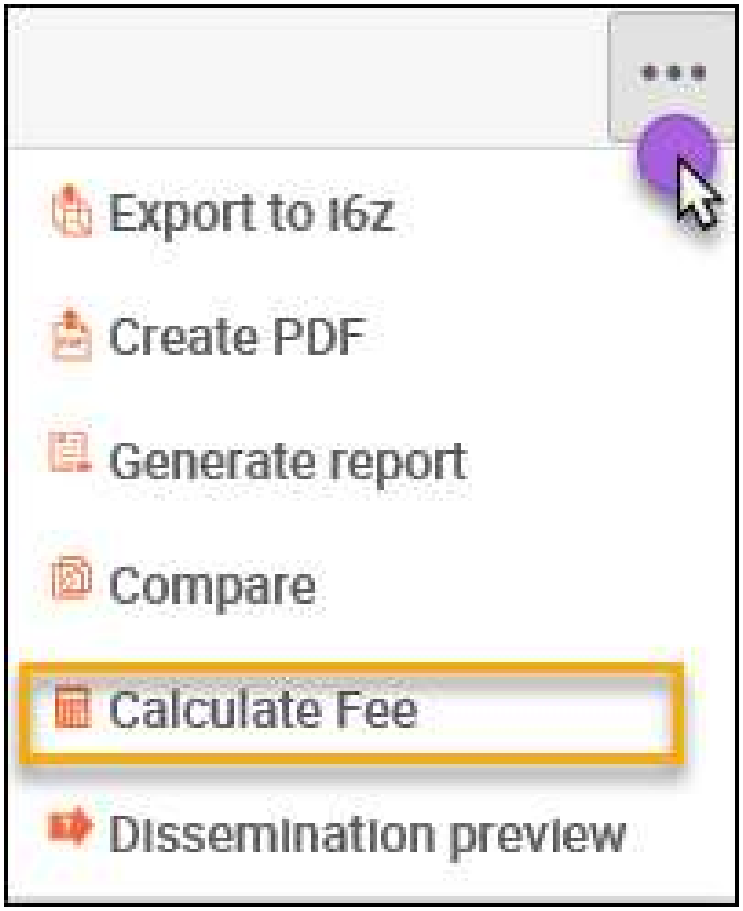
Dissemination preview

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



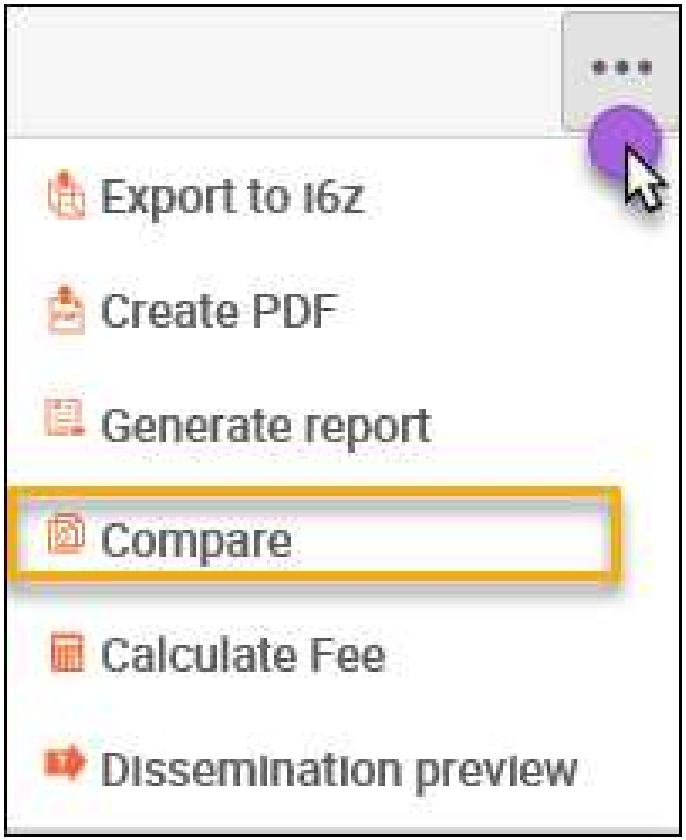
Fee calculator

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

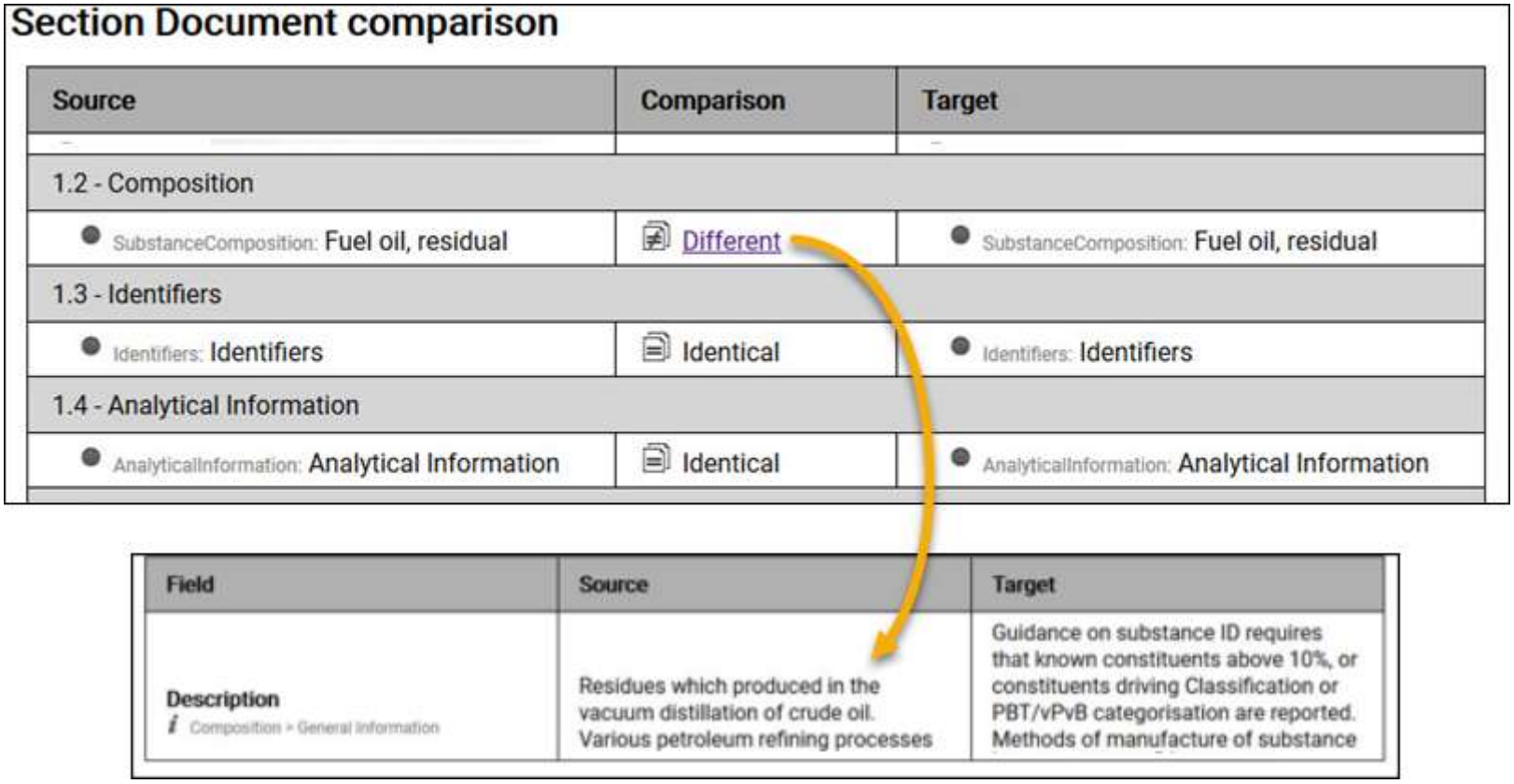


Comparison tool (1/2)

- 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)



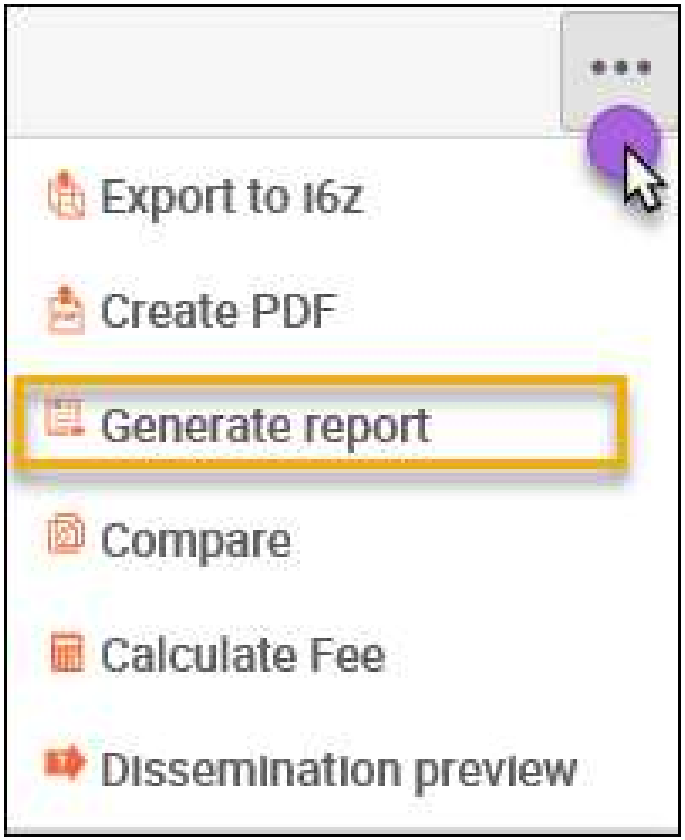
Section Document comparison

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 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

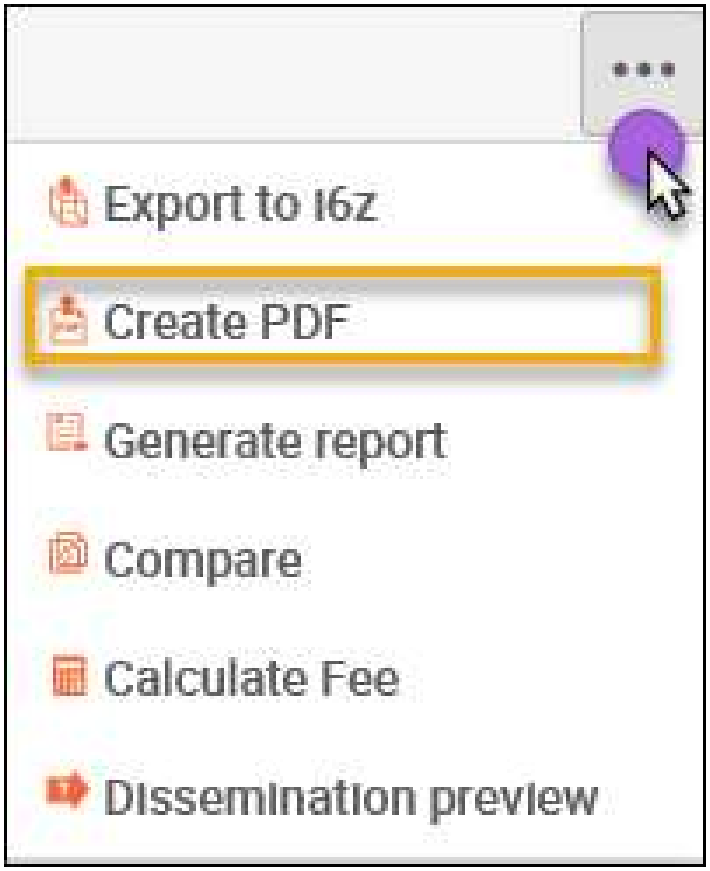
Report generator

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



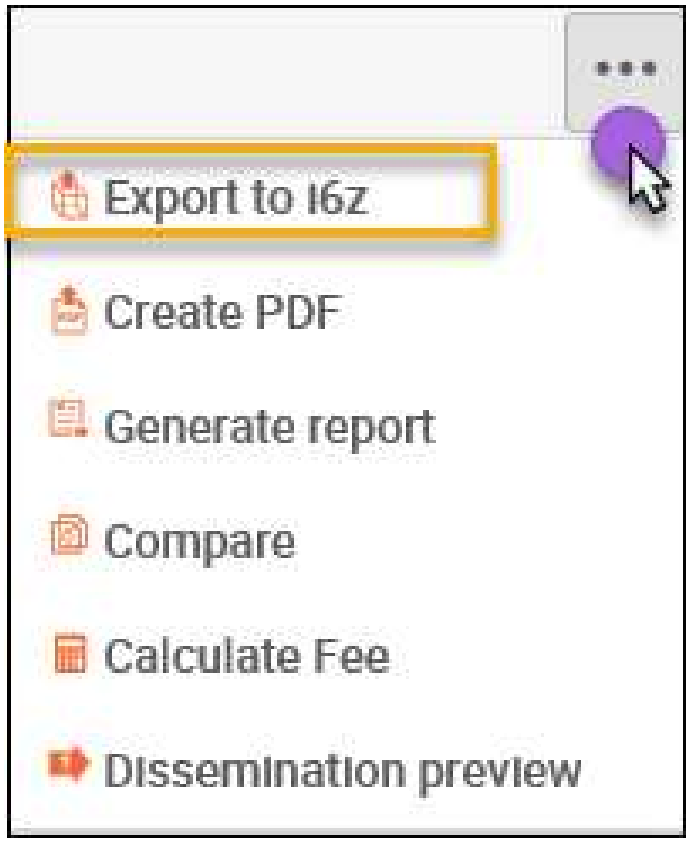
Create pdf

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



Export file

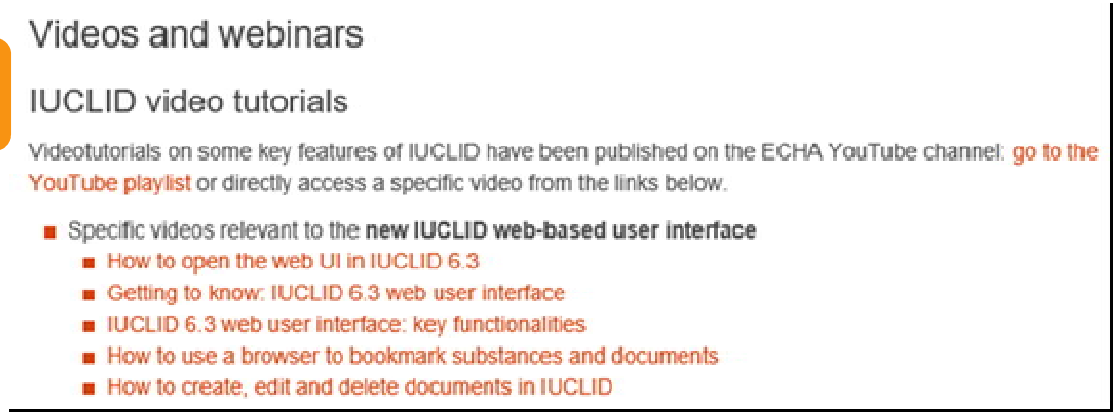
- To export the substance or the final dossier in .i6z format, e.g., for submission
- Available both on substance and dossier level



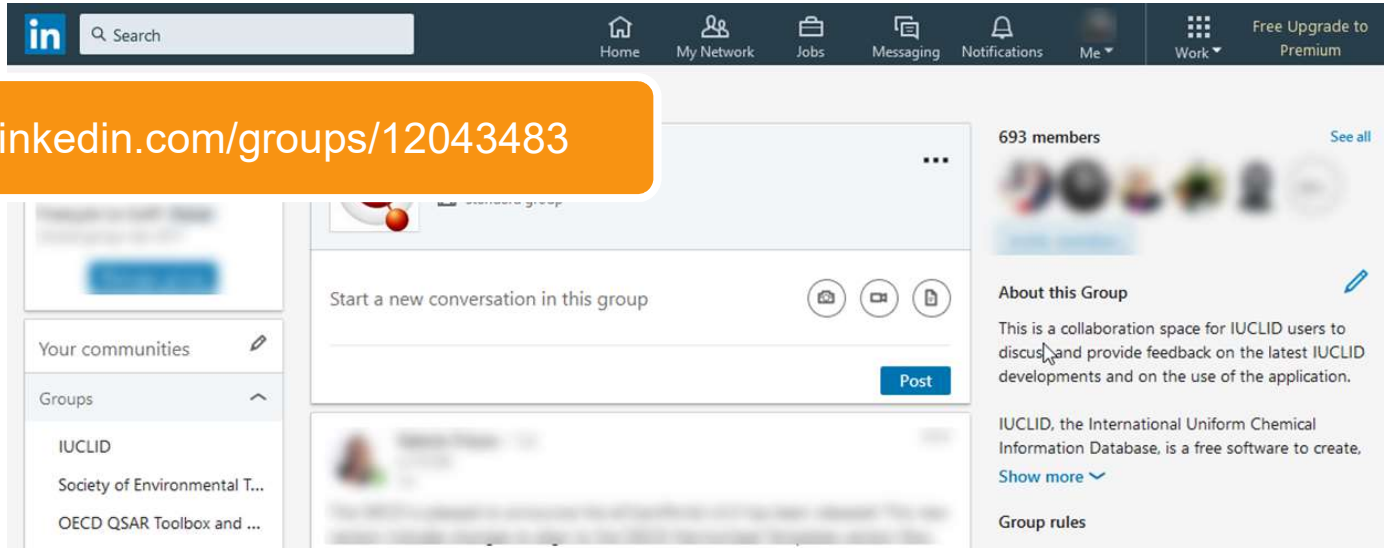
Support and feedback

More information on IUCLID web UI

iuclid6.echa.europa.eu



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

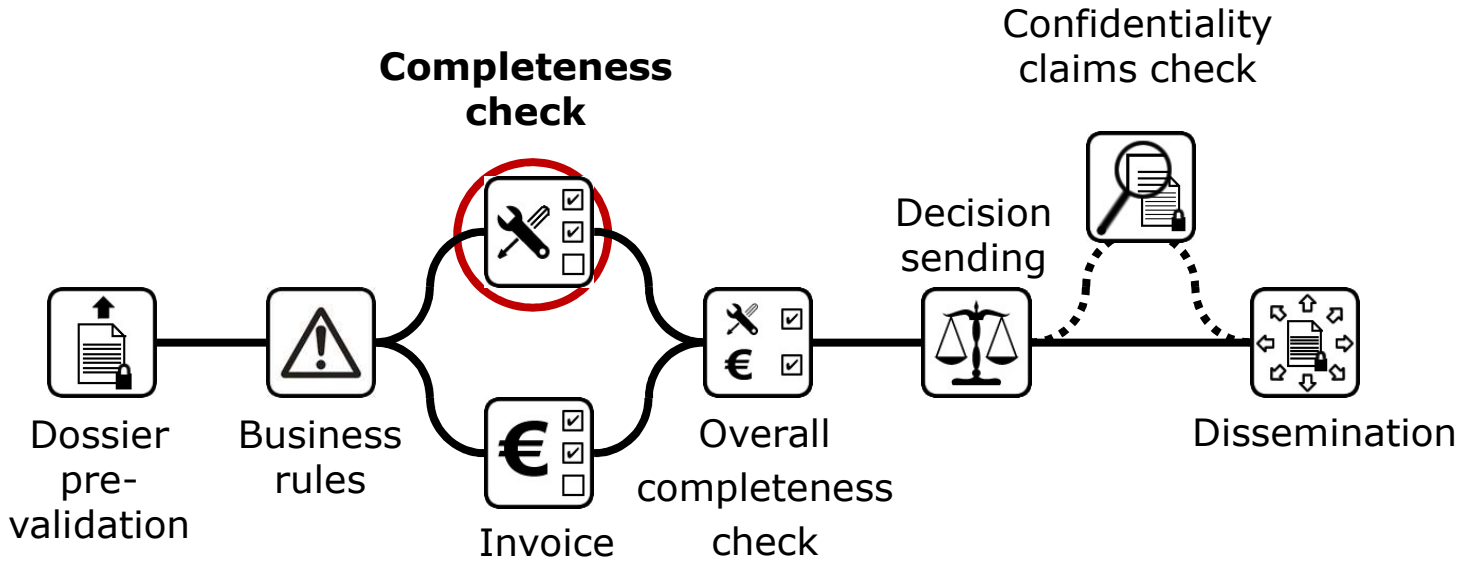
Completeness check

Manual verification

12 June 2019

Margot Mägi
Data Availability Unit
ECHA

Ccompleteness 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

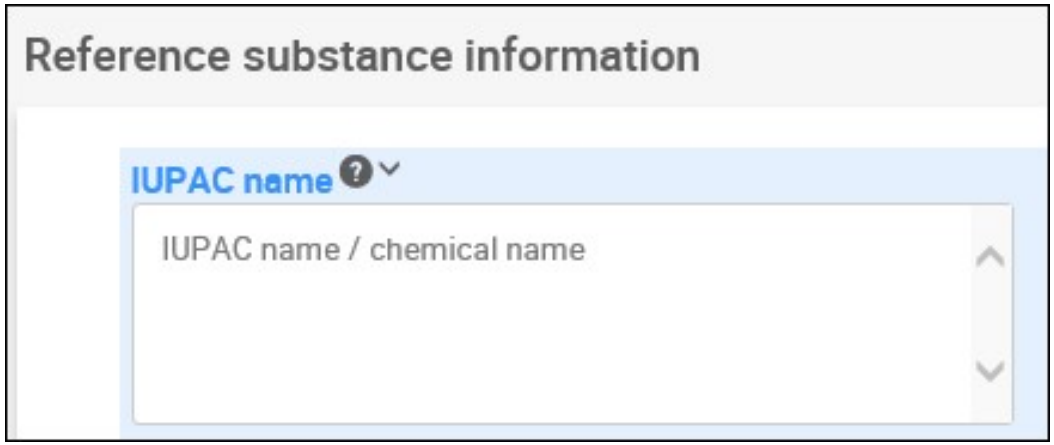
Substance identification

Areas of manual
Completeness checks

Substance identification (1/7)

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.



Substance identification (2/7)

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'.

Substance identification (3/7)

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.

Substance identification (4/7)

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.

Substance identification (5/7)

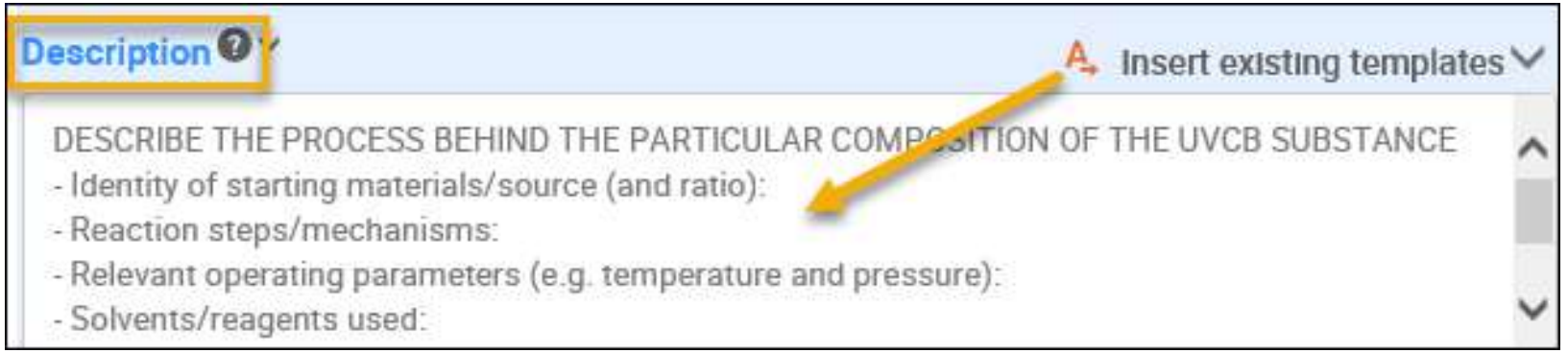
Composition of a UVCB substance

- 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'.

Substance identification (6/7)

Manufacturing process description of UVCB substance

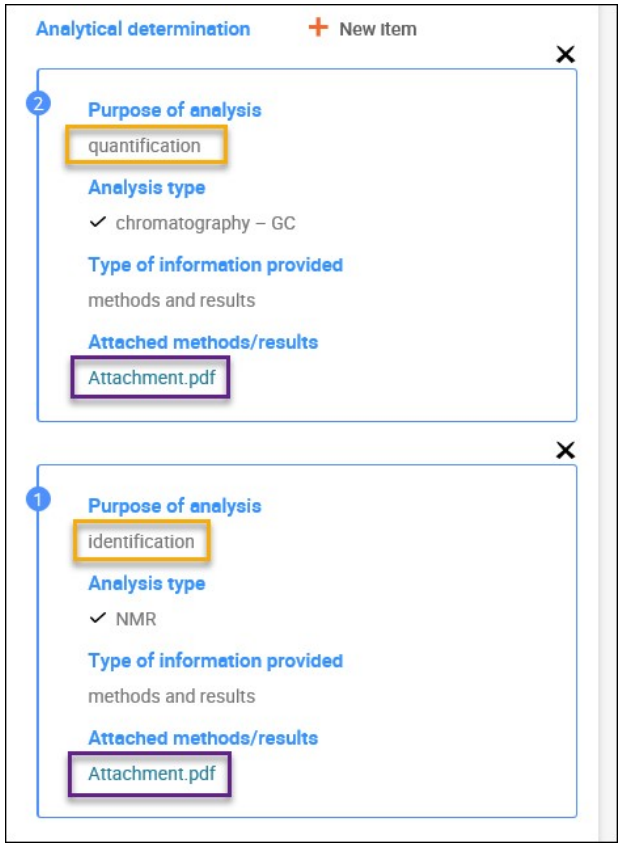
- A description of the source used and the process applied must be included in the 'Description' field in IUCLID section 1.2.
- Use the free text template of the IUCLID field marked with “A” to help you report relevant information.

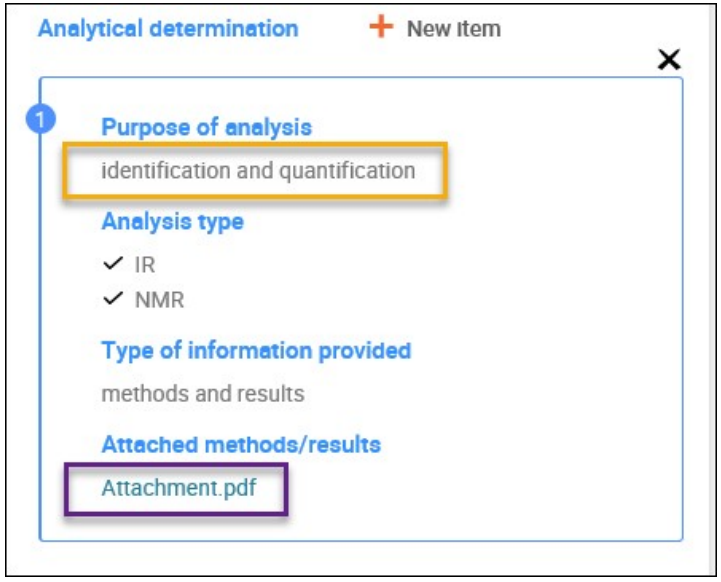


Substance identification (7/7)

Analytical information

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





Data waiving

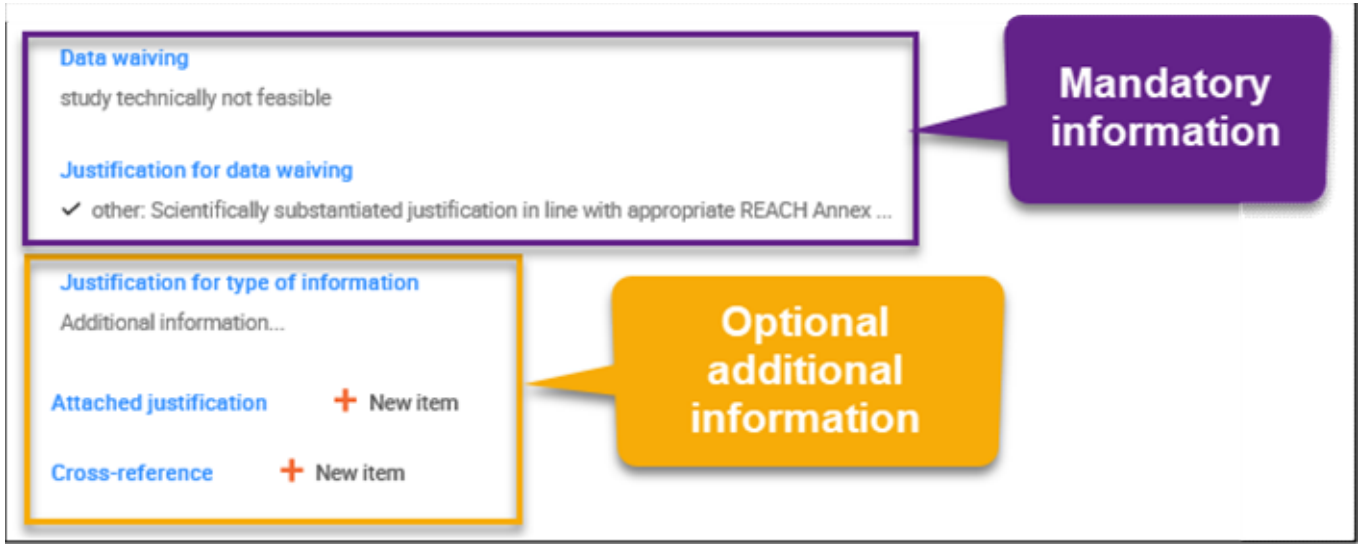
Areas of manual
Completeness checks

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."

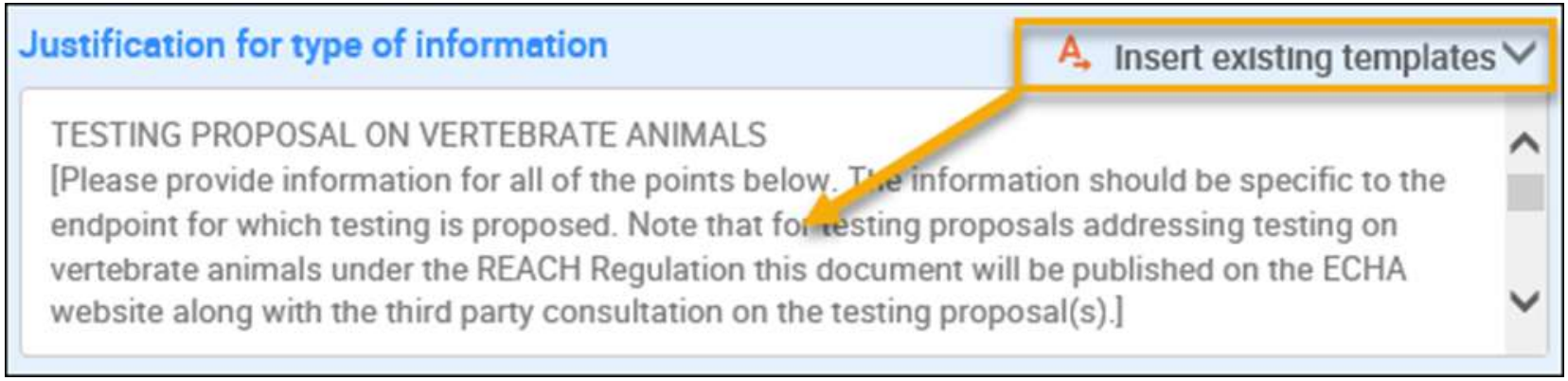
"There are no chemical groups associated with explosive properties in the molecule. For further details, see the expert report in the field 'Attached justification'."

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



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

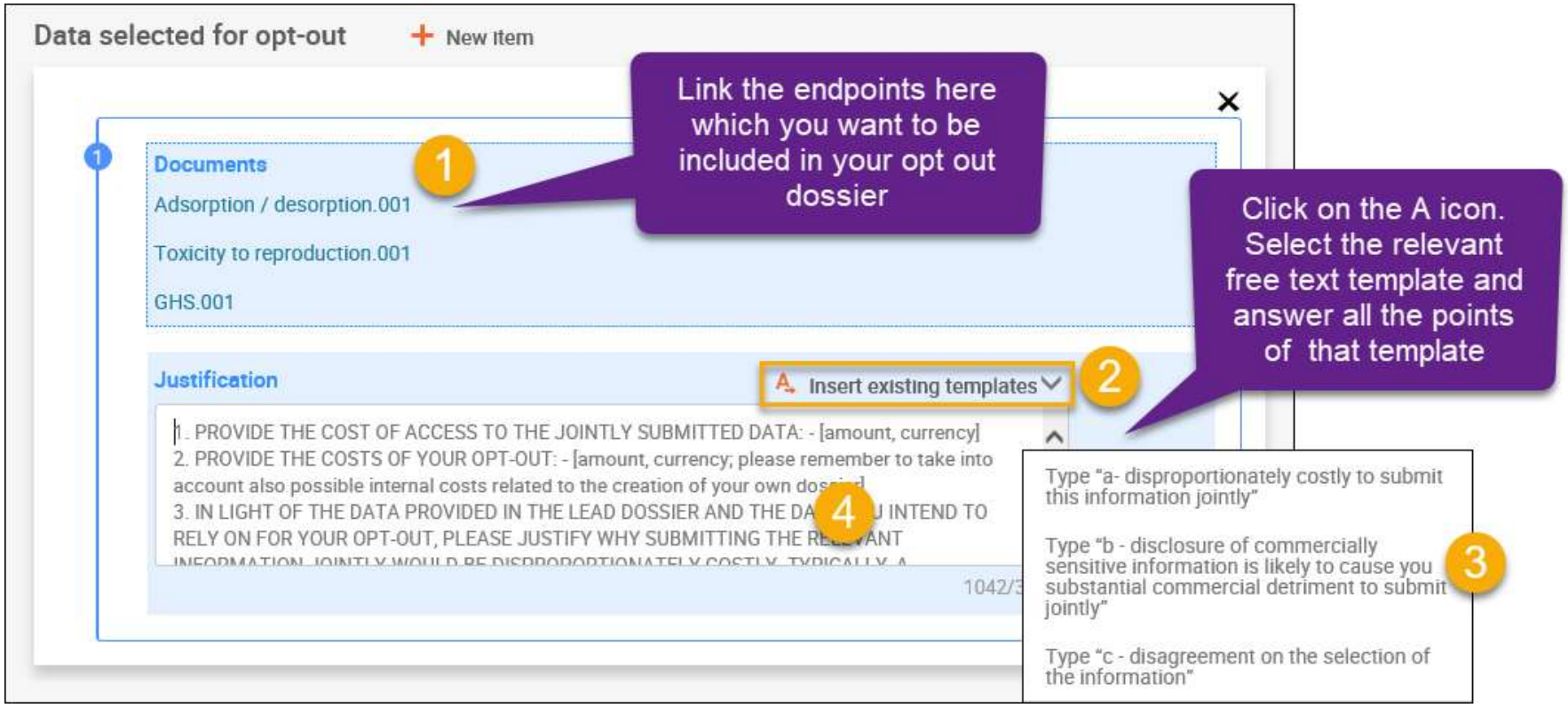
Areas of manual completeness checks

Opt-out justification (1/2)

- 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)



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

Support

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?

ECHA
EUROPEAN CHEMICALS AGENCY

Thank you!

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