# Completeness check: Preparing a registration dossier that can be successfully submitted to ECHA

ECHA webinar

20 April 2017

# Agenda

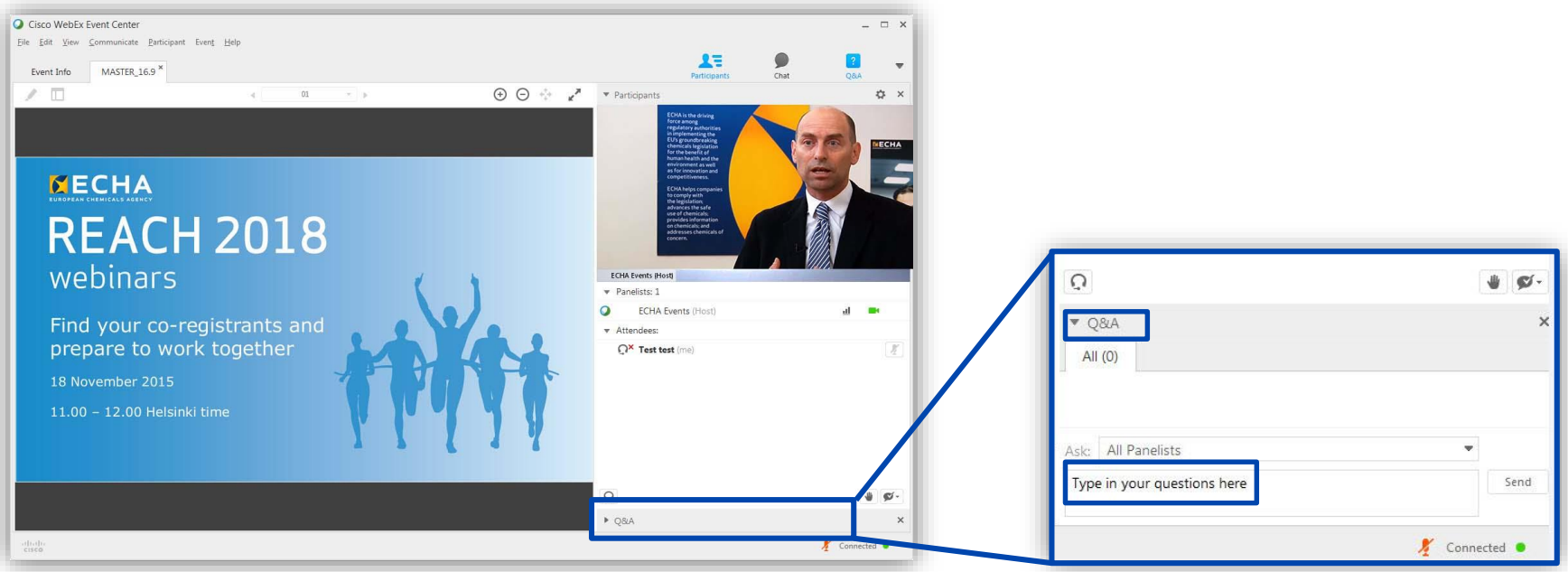
| | | |
|---|---|---|
| 11:00 | INTRODUCTION | Joost Rutten |
| 11:05 | COMPLETENESS CHECK PROCESS | Tamás Salamon |
| 11:15 | VALIDATION ASSISTANT | Tamás Salamon |
| 11:25 | MANUAL CHECKS | Essi Numminen |
| 11:45 | COMMON CASES & SUPPORT | Tiphaine Paris |
| 11:55 | CONCLUSIONS | Joost Rutten |
| 12:00 | TIME FOR ANSWERING QUESTIONS | |

# Questions and answers

- Q&A panel open from 11:00 to 13:00
- You can submit questions until 12:30
- If question not answered by 13:00 -> re-submit using our contact form: echa.europa.eu/contact
- A few common questions will be answered verbally at the end of the webinar (11:55)
- Webinar recording and presentations sent to you after the webinar
- Most frequent questions and answers added to the our Q&A page

# Questions and answers

- Panellists respond to your questions directly through Q&A panel
- Monitor Q&A panel for response and remain logged-in to the webinar until you receive it

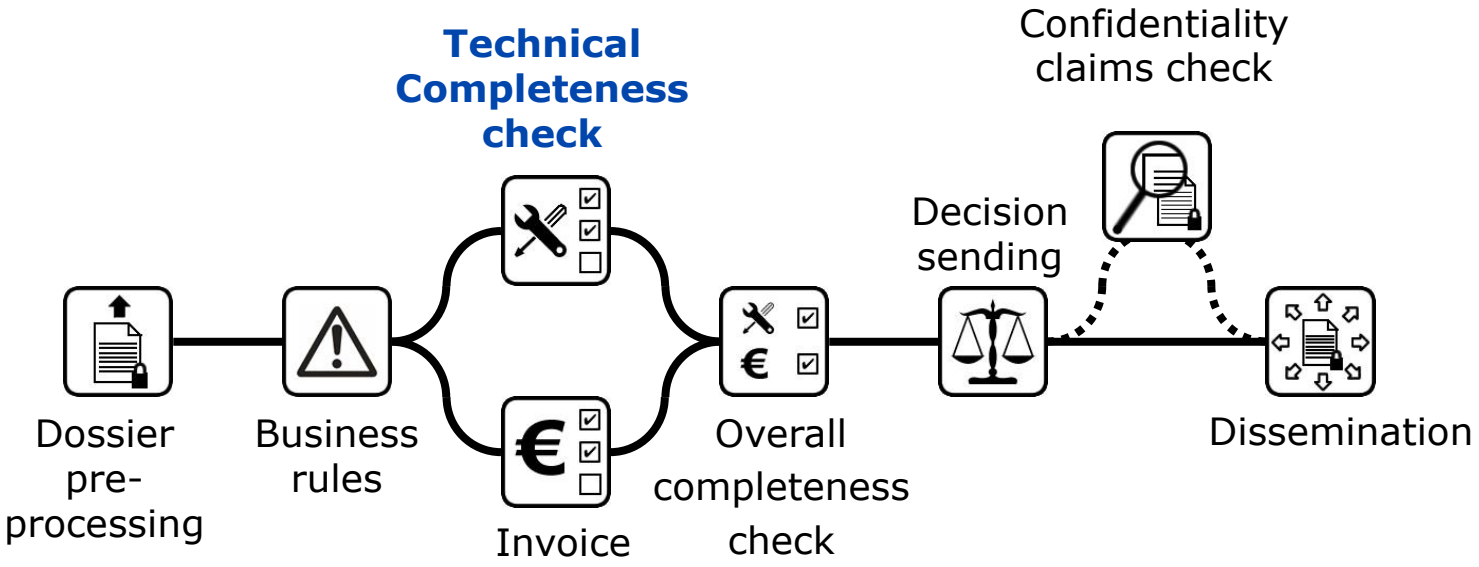


# Questions and answers

- The character limit of a question is 256 characters
- Submit questions related to webinar topic
- Do not include confidential business information
- We cannot answer questions on specific submissions - you can send those using our contact form: echa.europa.eu/contact
- If you experience difficulties with the webinar tool, contact our support team via the Q&A panel or by sending an email: conference@echa.europa.eu

# Completeness check process

# Submission process




Submission process in REACH-IT

# Completeness check

- Completeness check ensures all required elements are in the registration dossier as per Article 20(2)
- Completeness check is performed on each registration dossier submitted to ECHA – both initial and update submissions

# Completeness check

- 2010: REACH information requirements converted into automated completeness check rules
- 21 June 2016: enhanced completeness check enters into force: revised automated rules and additional manual checks performed by our staff
    - Manual checks mean completeness check takes a bit longer than before (max. three weeks)
    - If you are planning to update your registration and the previous dossier was submitted using IUCLID 5 you may need to revise the data before submitting it in IUCLID 6 format

    Reserve some time for this!
- ECHA does not foresee to modify the completeness check further before 2018 deadline

# Completeness check outcome

Technical completeness check (TCC) passes 

- Message from ECHA in REACH-IT
- If the payment (if invoice was issued) 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:** we accept the updated information in the database

# Completeness check outcome

Failure of technical 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

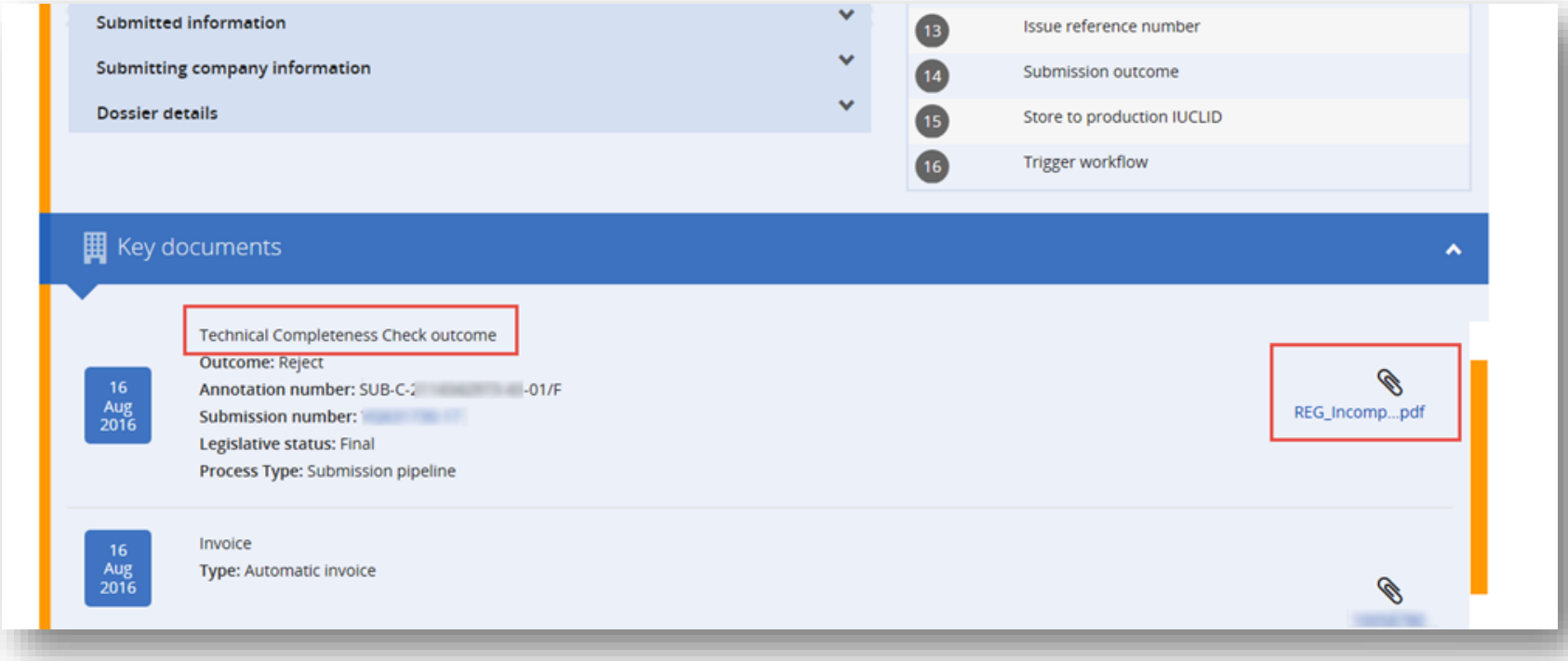
# Completeness check outcome

Failure of technical completeness check 2nd time 

- 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**
  - Updated information not accepted into ECHA database and subsequent processes
  - You keep your registration number
- After rejection you can submit a new dossier for the substance

# Technical completeness check letter

- After 1st failure of technical completeness check
- Found on submission page under “key documents”

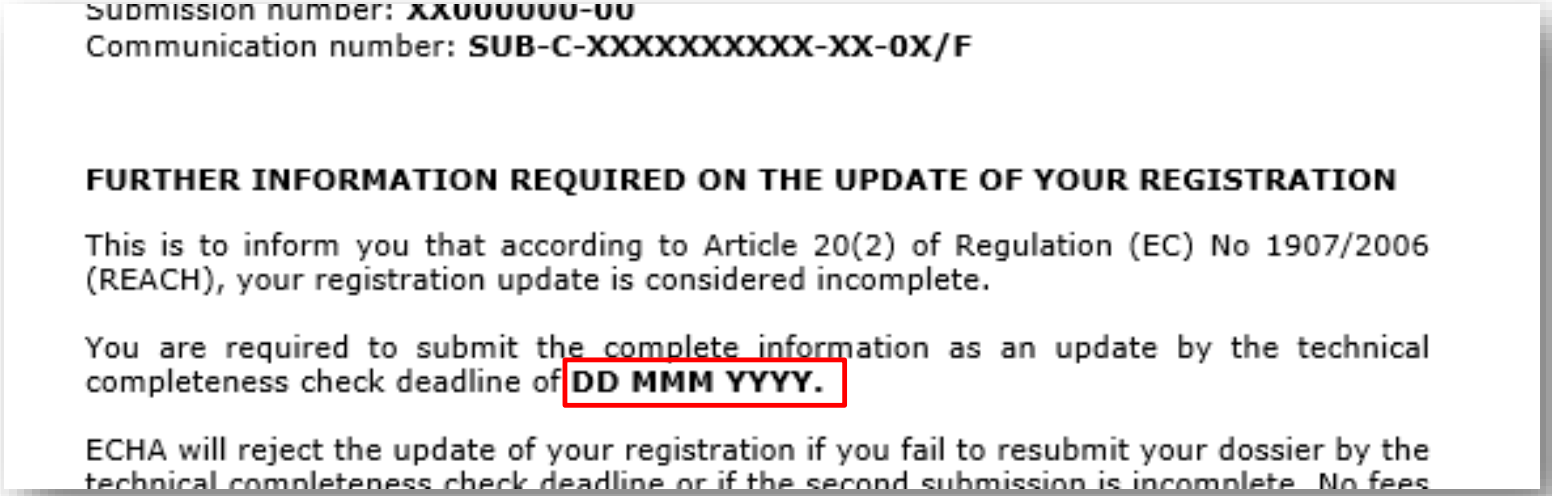


# Technical completeness check letter

- Deadline by when you are requested to correct failures and re-submit your dossier
- Annex 1 with detailed information about causes of incompleteness and instructions for correcting failures
- Annex 2 with instructions for creating update dossier and validating it before submitting it in REACH-IT

# Technical completeness check letter

- Deadline to correct failures and submit improved dossier



Submission number: **XX000000-00**
Communication number: **SUB-C-XXXXXXXXXX-XX-0X/F**

**FURTHER INFORMATION REQUIRED ON THE UPDATE OF YOUR REGISTRATION**

This is to inform you that according to Article 20(2) of Regulation (EC) No 1907/2006 (REACH), your registration update is considered incomplete.

You are required to submit the complete information as an update by the technical completeness check deadline of **DD MMM YYYY.**

ECHA will reject the update of your registration if you fail to resubmit your dossier by the technical completeness check deadline or if the second submission is incomplete. No fees

# Technical completeness check letter

**Annex 1: Missing information**

**Section 5.2.2 Biodegradation in water and sediment: simulation tests** - Biodegradation in water and sediment_waiver - Section 5.2.2: 'Administrative data' is not complete. For each endpoint study record marked as a 'Data waiving', a valid justification for not fulfilling the standard information requirement must be provided in the field 'Justification for data waiving'. Sections 2 and 3 of Annex XI of REACH and Columns 1 and 2 of the relevant endpoint in Annexes VII to X provide reasons why a study would not need to be submitted in the dossier. The justification you provided for not submitting the study required is not one of these reasons and it is not considered as valid by ECHA. ECHA can therefore not take this justification into account.

You will find below the options available to fulfil this REACH requirement:

- Provide the standard required study; or
- Provide a testing proposal and ensure to include the considerations for alternative methods (only for fulfilling an Annex IX or X information requirement); or
- Provide an adaptation according to Section 1 of Annex XI (Use of existing data, weight of evidence, (Q)SAR, in vitro methods, grouping of substances and read-across approach); or
- Provide a data waiving based on columns 2 of Annexes VII to X; on sections 2 or 3 of Annex XI (Testing technically not possible, substance-tailored exposure-driven testing) or on any other valid reasons that is fully substantiated:
  - By selecting a relevant value from the picklist in the field 'Justification for data waiving'; or
  - If none of the available picklist values from the field 'Justification for data waiving' apply, select 'other:' and insert a valid explanation for the data waiving in the adjacent free-text field.

For further information consult the supporting document below on how to provide information under REACH:

How to prepare registration and PPORD dossiers
http://echa.europa.eu/manuals

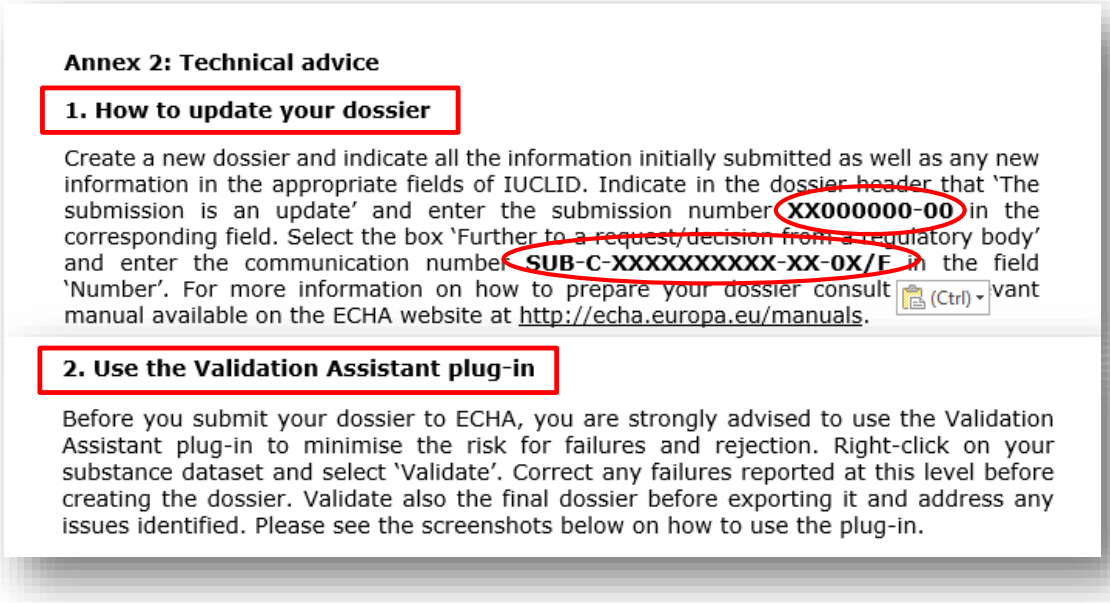
Endpoint specific guidance R7a, R7b and R7c
https://www.echa.europa.eu/guidance-documents/guidance-on-information-requirements-and-chemical-safety-assessment

**This failure was detected as part of the additional verifications by ECHA staff and therefore cannot be displayed by the Validation Assistant plug-in.**

## Annex 1

- Failing section and document name
- Description of failure
- Instructions on how to correct
- Reference to relevant support material
- Indication of whether failure can be detected by Validation assistant tool

# Technical completeness check letter



**Annex 2: Technical advice**

**1. How to update your dossier**

Create a new dossier and indicate all the information initially submitted as well as any new information in the appropriate fields of IUCLID. Indicate in the dossier header that 'The submission is an update' and enter the submission number **XX000000-00** in the corresponding field. Select the box 'Further to a request/decision from a regulatory body' and enter the communication number **SUB-C-XXXXXXXXXX-XX-0X/F** in the field 'Number'. For more information on how to prepare your dossier consult (Ctrl) vant manual available on the ECHA website at http://echa.europa.eu/manuals.

**2. Use the Validation Assistant plug-in**

Before you submit your dossier to ECHA, you are strongly advised to use the Validation Assistant plug-in to minimise the risk for failures and rejection. Right-click on your substance dataset and select 'Validate'. Correct any failures reported at this level before creating the dossier. Validate also the final dossier before exporting it and address any issues identified. Please see the screenshots below on how to use the plug-in.

## Annex 2

- Instructions on how to submit a dossier in response to technical completeness check letter
- Reminder to use Validation assistant

## Important

- Use correct submission and communication numbers, otherwise you will fail at business rules step

# Technical completeness check letter

**Important**

- Read failure descriptions carefully in Annex 1 of the letter and follow instructions for correcting failures
- Use available support
- Correct **all** failures listed in the letter before submitting the next dossier
- Contact us well before technical completeness check deadline if not sure how to correct failures

# Tips for 2018 deadline

- Close to deadline, receiving technical completeness check outcome can take longer
- Members of a joint submission can submit their dossier as soon as lead registrant has passed business rules check
- Member dossiers only declared complete and get a registration number once lead dossier has passed completeness check, as they rely on the information to be complete
- If your dossier fails at completeness check, you have only one possibility to update the dossier within that submission

# Validation assistant

# Validation assistant

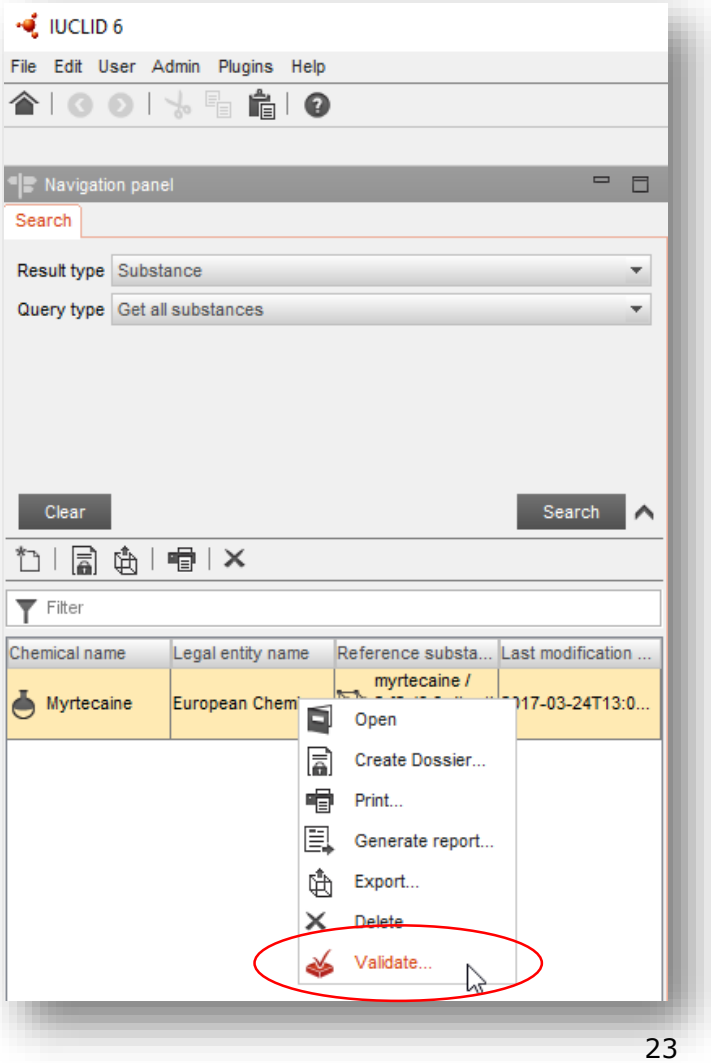
- Plug-in available in IUCLID
- Assists you in preparing IUCLID dossiers
- Carries out validations on datasets and dossiers to verify that information provided as expected
- Outcome of the validation is a report listing all rules for which the validation failed

# Validation assistant

- Use Validation assistant before you submit your dossier to minimise risk for failures and rejection
  - Check your substance dataset (before dossier is created) to correct any already reported failures reported
  - Check final dossier before submitting it
- Never submit your dossier if there are still failures given by the Validation assistant: your dossier will fail either at business rules or completeness check stage

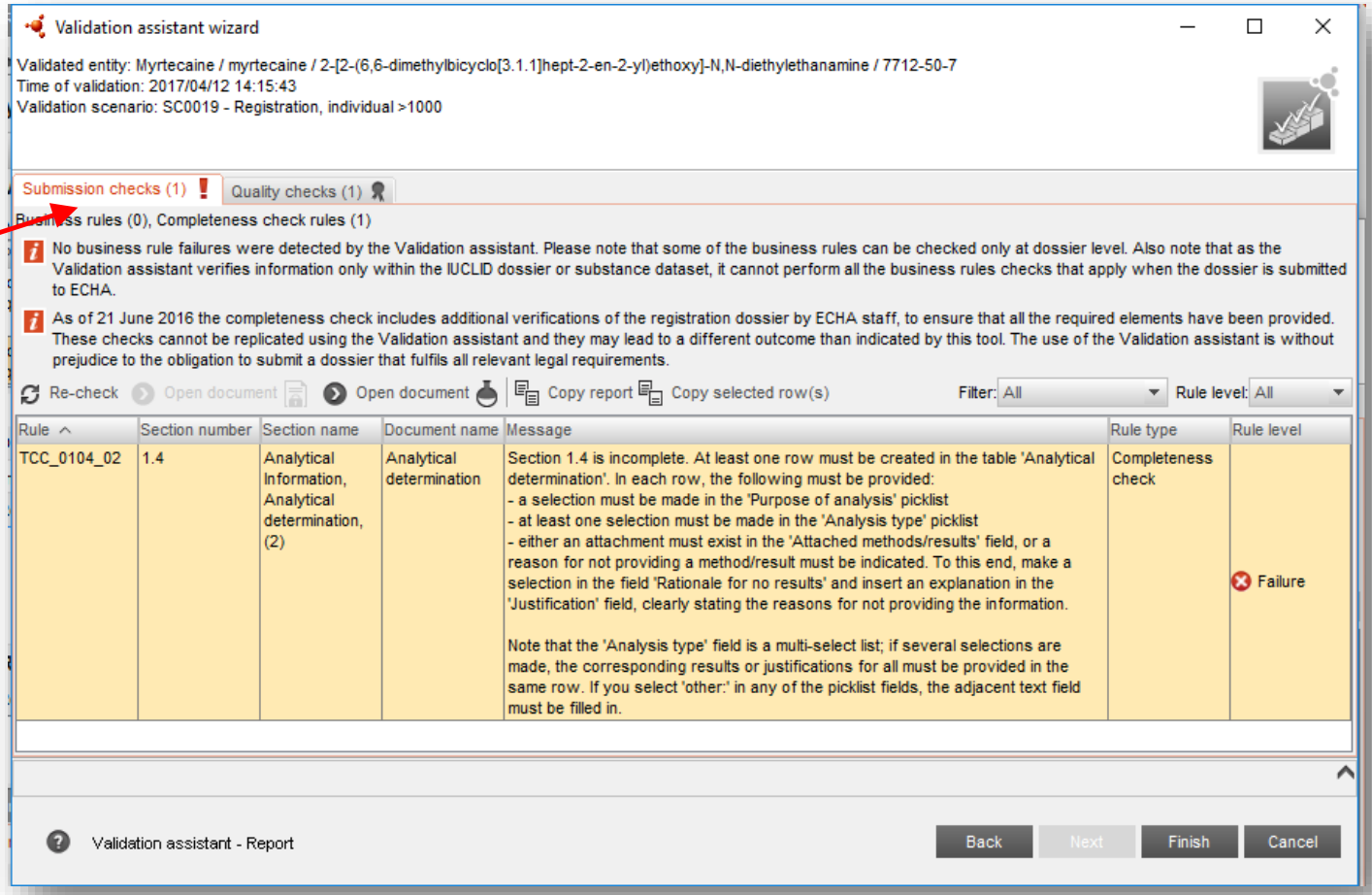
# Running the validation assistant

- Access substance dataset
- Right-click on dataset and select ‘Validate’
- Provide information requested by the tool in the next steps



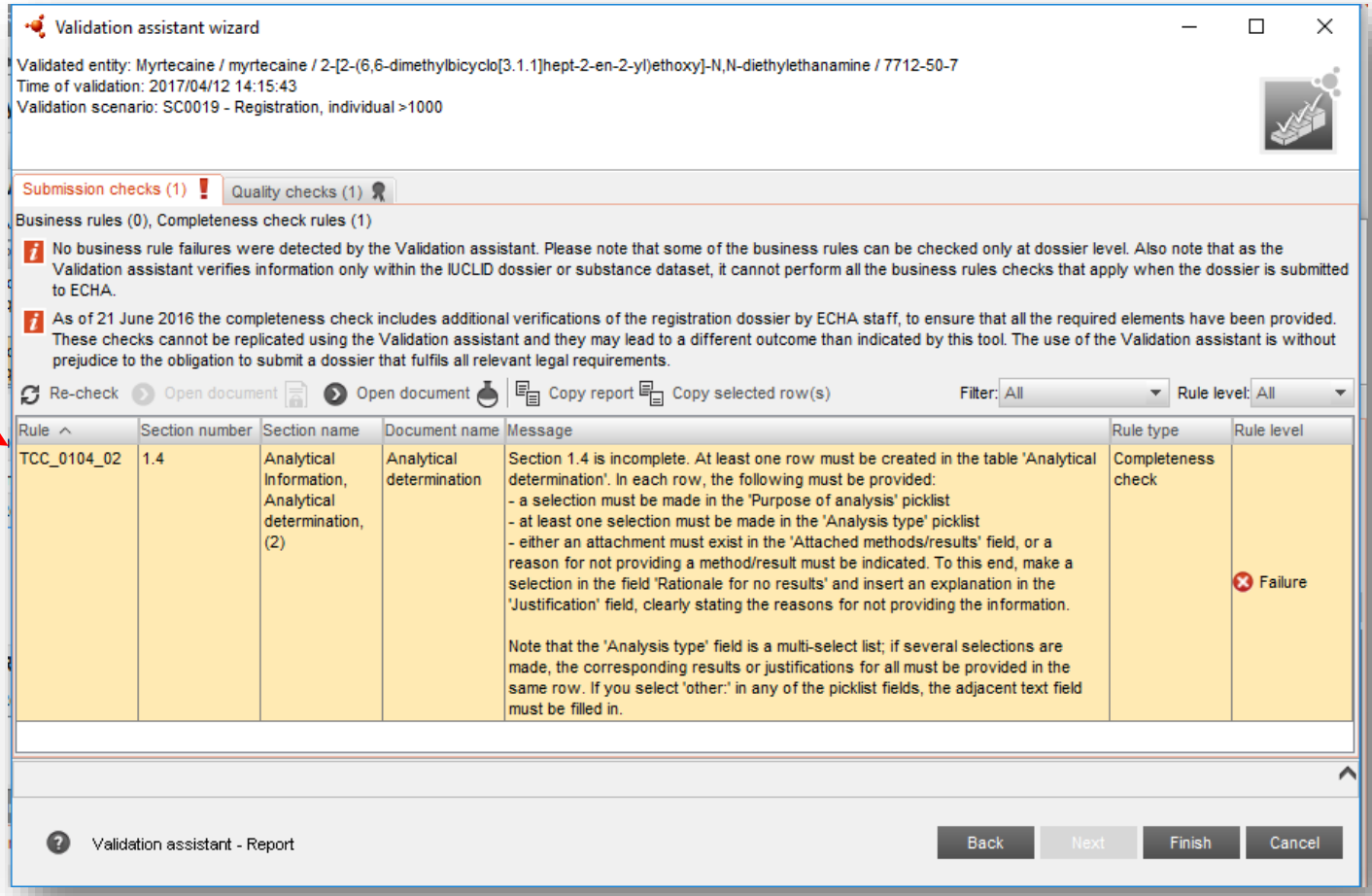
# Validation assistant results

Total number of submission check failures



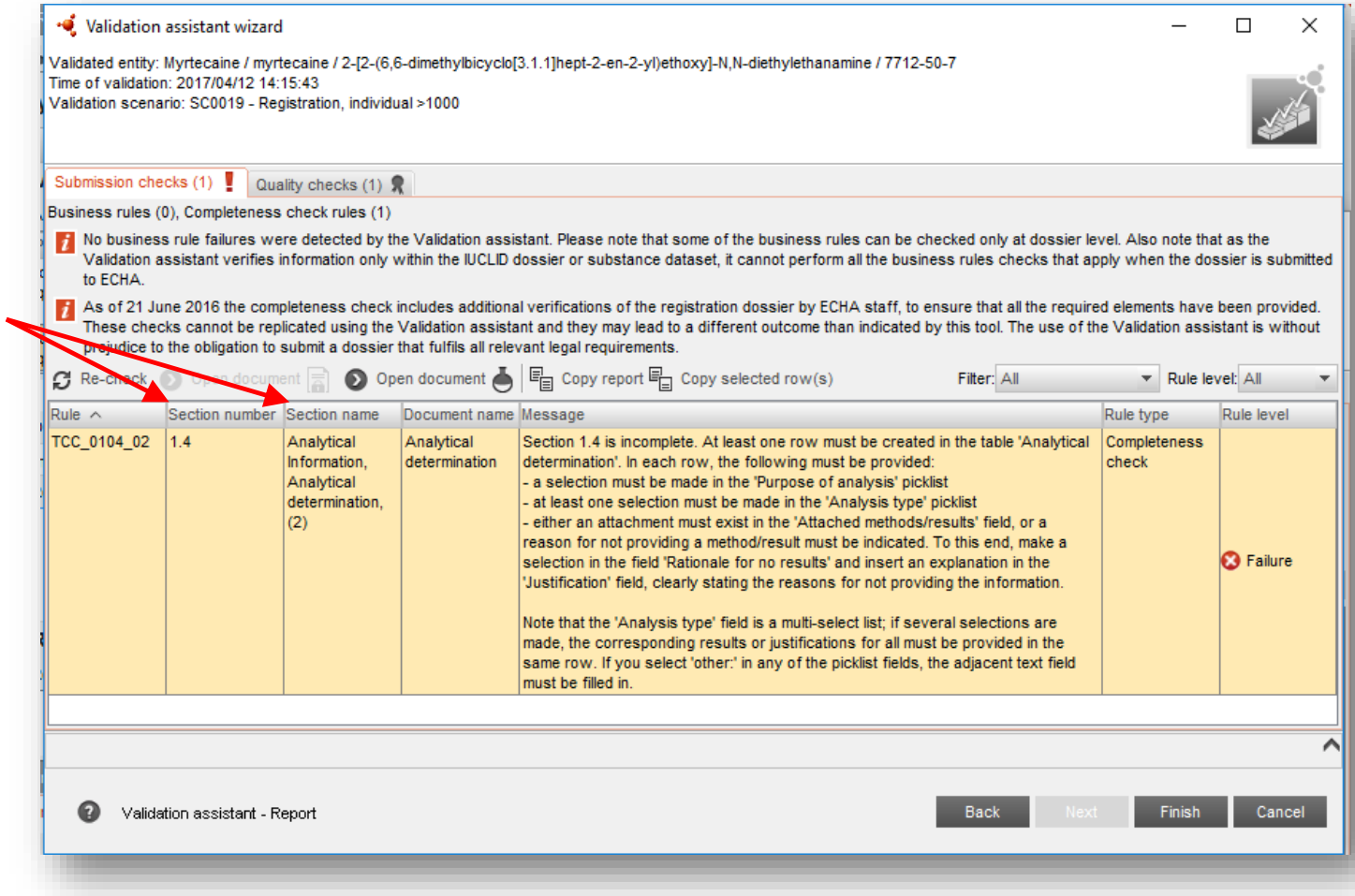
# Validation assistant results

Rule ID



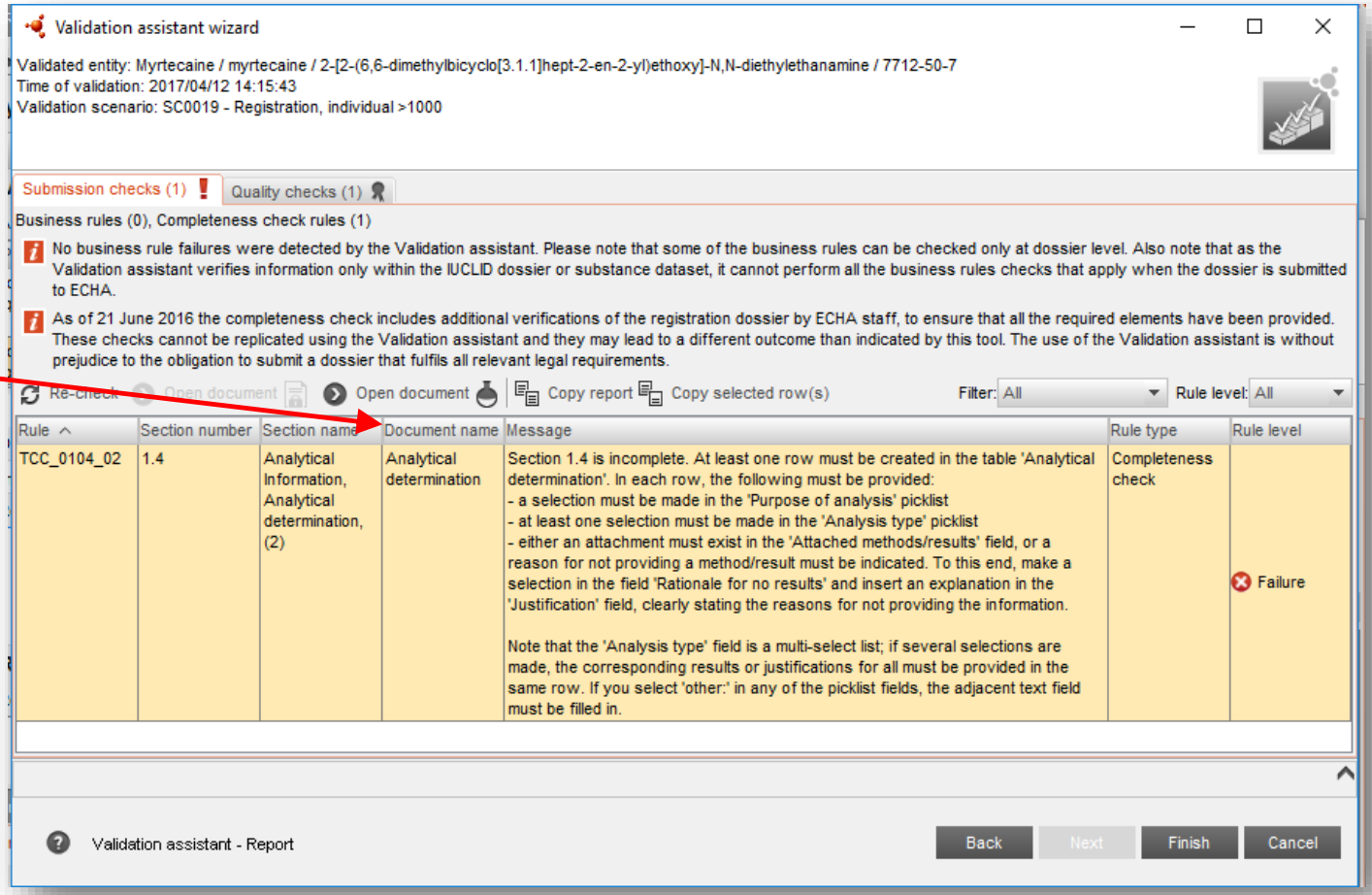
# Validation assistant results

Failing IUCLID section number and name



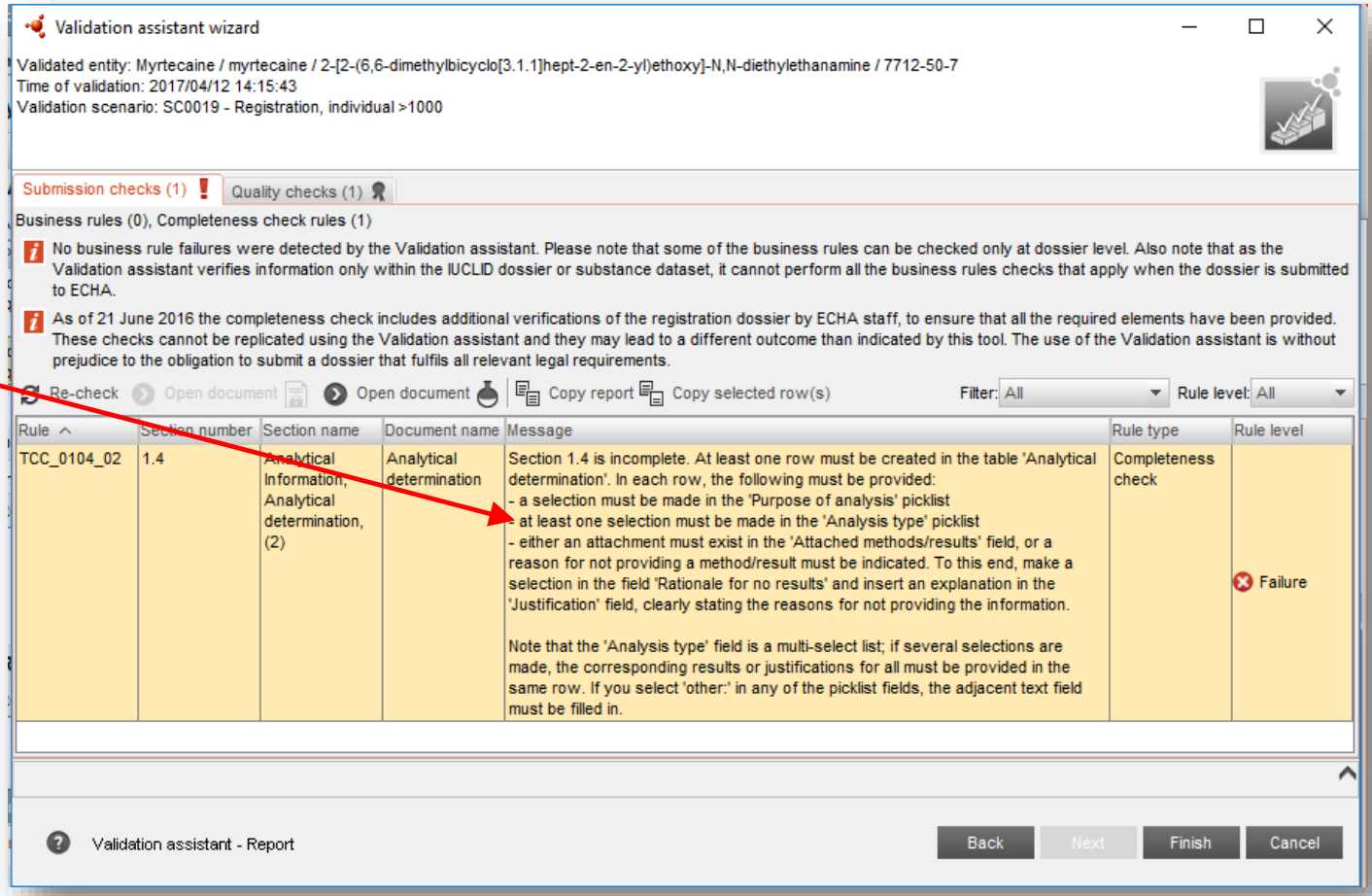
# Validation assistant results

Name of failing document (endpoint study record or other record)



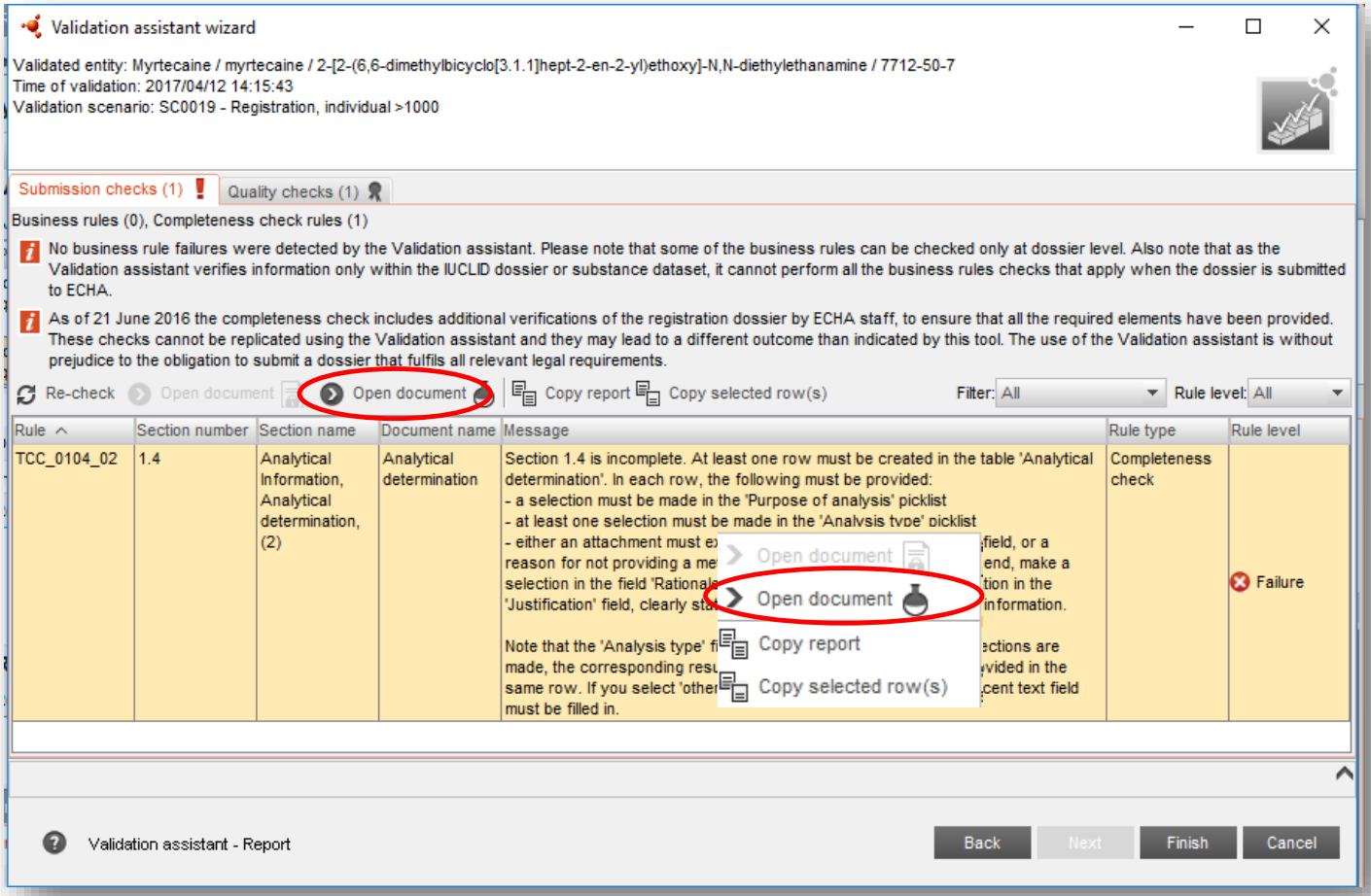
# Validation assistant results

Failure description



# Validation assistant results

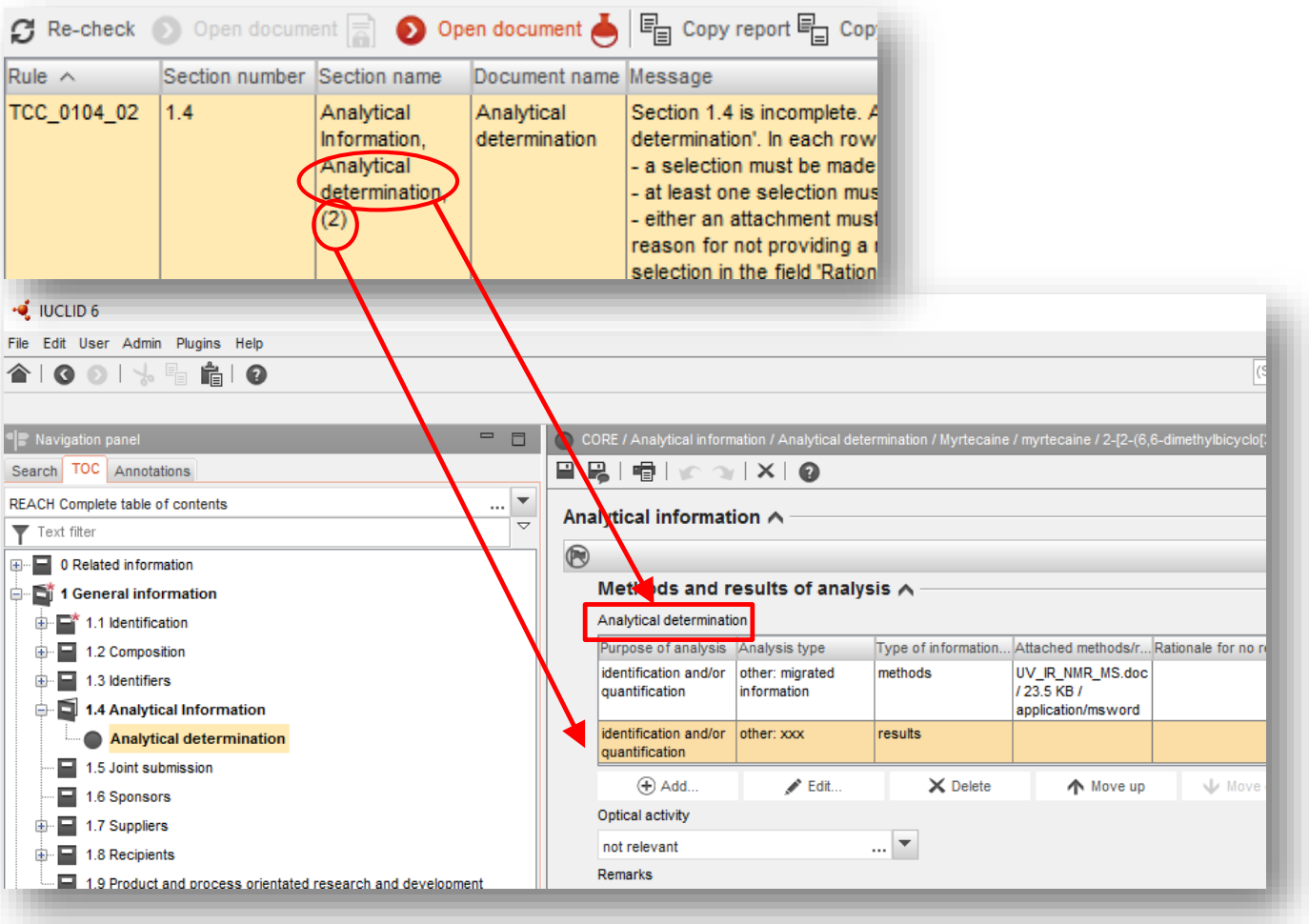
Navigate to failing document



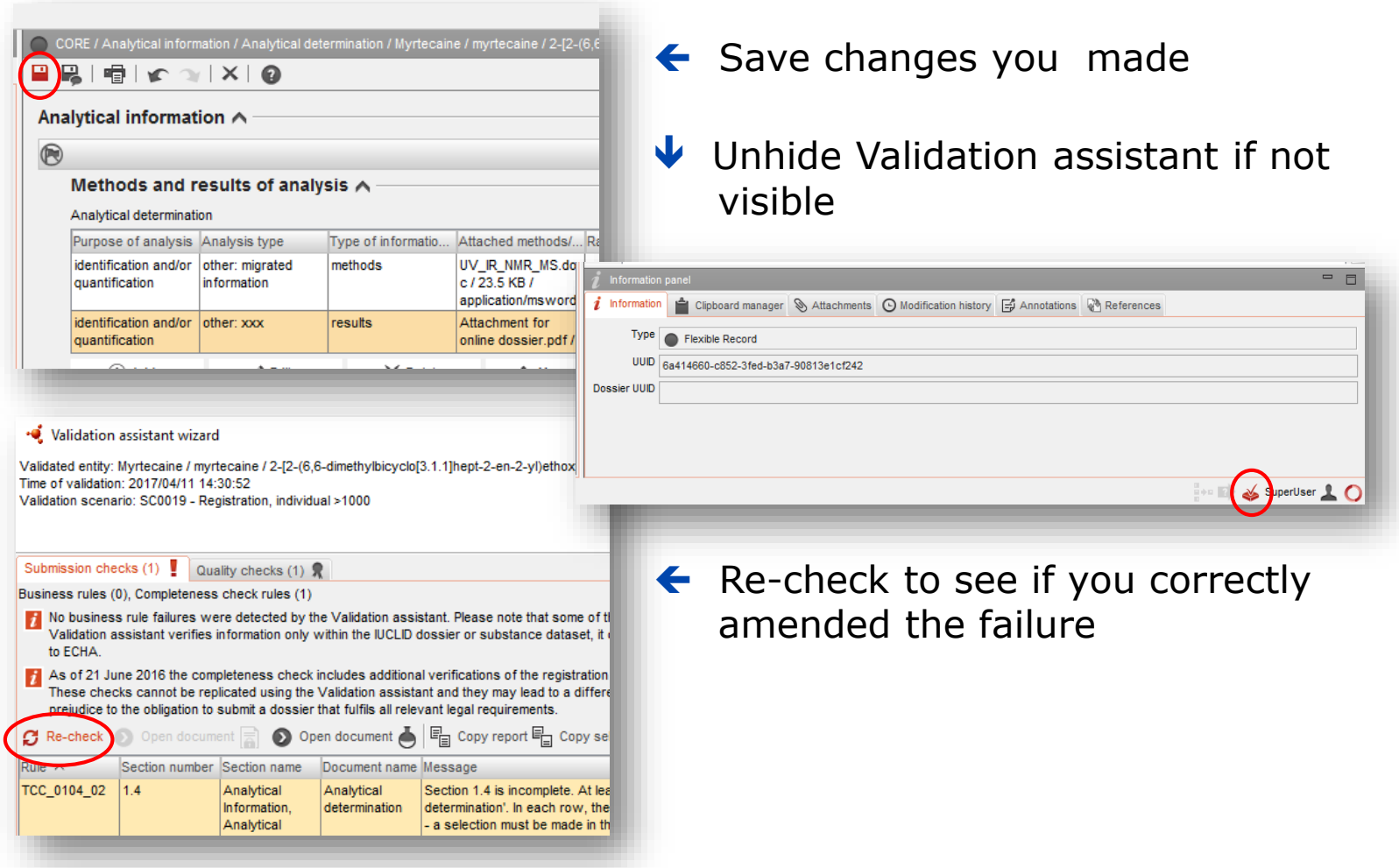
# Locate failure source

Name of failing table

Failing row number



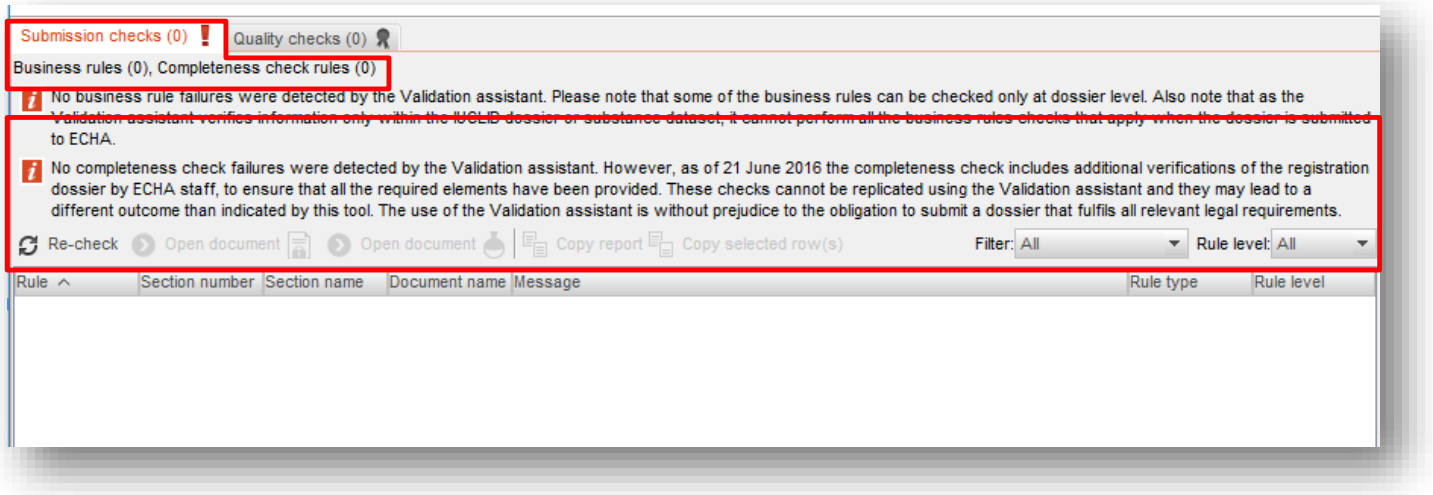
# Correct, save and re-check




- Save changes you made
- Unhide Validation assistant if not visible
- Re-check to see if you correctly amended the failure

# Validation assistant

- Correct all failures indicated by the Validation assistant
- Do not submit dossier before all **'Submission checks'** failures are fixed




- Additional checks performed by our staff that the Validation assistant cannot predict

# Manual checks as part of the completeness check

# Manual checks at completeness check

- As of 21 June 2016, automated completeness check complemented with additional manual checks by our staff of certain elements of the registration dossier that cannot be checked automatically
- Not displayed by Validation assistant
- Scope of manual checks is completeness, not quality or compliance; to ensure that registrants who deviate from standard requirements provide a justification that is relevant within the REACH context
- Document with information on manual checks: echa.europa.eu/manuals

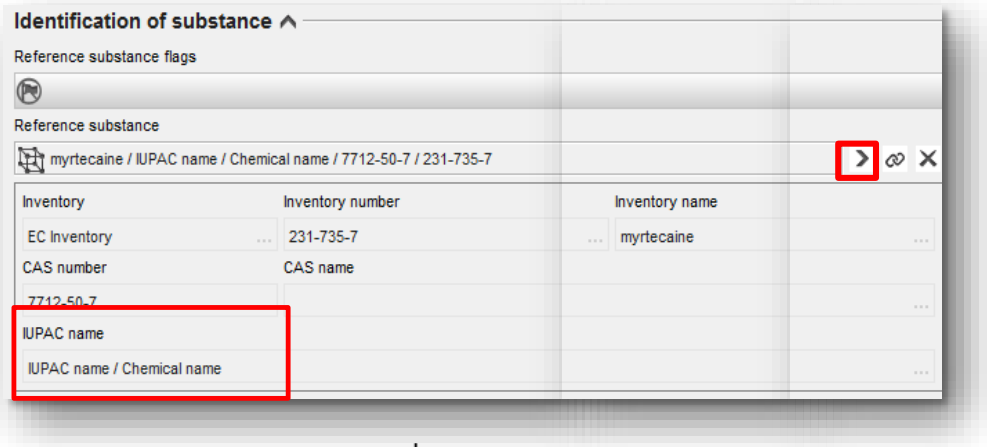
# Current focus of manual checks

- Substance identification (IUPAC name, composition, manufacturing process description of UVCB substances, analytical information)
- Justification for waiving standard information requirements (physicochemical, environmental fate, hazard, toxicological and ecotoxicological information)
- Testing proposals on vertebrate animals (presence of considerations for adaptation possibilities)
- Justification for waiving chemical safety report

# Substance identification

IUPAC name of the registered substance

- IUPAC name must be provided in 'IUPAC name' field in IUCLID section 1.1 - Reference substance
  - In case registered substance has no official IUPAC name, chemical name must be provided in IUPAC name field
  - For multi-constituent and UVCB substances, consult Q&A 1197 and Q&A 1196



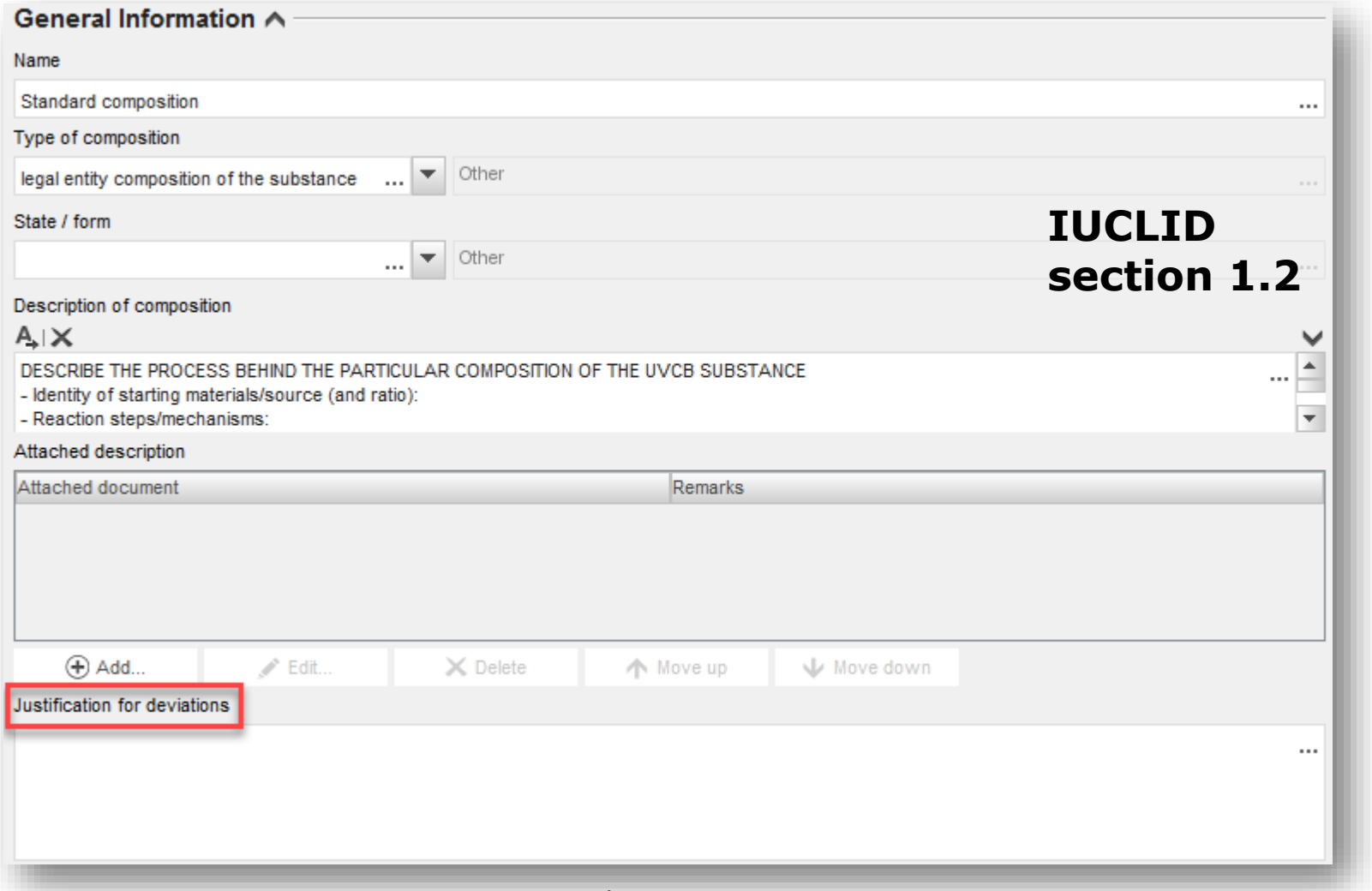
# Substance identification

## Number of constituents

| Mono-constituent | Multi-constituent |
| --- | --- |
| • Each reported composition is expected to contain only one constituent<br>• Reporting of multi-constituent composition in a mono-constituent dossier required in specific cases and must be justified under 'Justification for deviations'.<br>• See chapter 4.2.2 of Guidance on substance identification and naming*, and 9.4.2 of the manual: How to prepare registration and PPORD dossiers | • Each reported composition expected to contain more than one constituent<br>• Deviations from reporting constituents of a multi-constituent substance separately is exceptional and must be justified under 'Justification for deviations'<br>• See specific case examples of certain isomers in Q&A 1198 and hydrates in Q&A 1201 |

*Guidance for identification and naming of substances under REACH and CLP: http://echa.europa.eu/guidance-documents/guidance-on-reach

# Substance identification



# Substance identification

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

| Main constituent min 80% | Impurities max 20% |
| --- | --- |
| • For a mono-constituent substance, main constituent is expected to be present in each reported composition as a minimum at 80% (concentration range and/or typical concentration)<br>• If registered substance deviates from this rule, scientifically substantiated reason must be given in the 'Justification for deviations' field | • For a mono-constituent substance, impurities expected to be present in each reported composition as a maximum at 20% (concentration range and/or typical concentration)<br>• If registered substance deviates from this rule, scientifically substantiated reason must be given in the 'Justification for deviations' field |

*Guidance for identification and naming of substances under REACH and CLP: http://echa.europa.eu/guidance-documents/guidance-on-reach

# Substance identification

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

| Main constituent max 80% | Impurities max 10% |
| --- | --- |
| • For a multi-constituent substance, main constituents expected to be present in each reported composition as a maximum at 80% (concentration range and/or typical concentration)<br>• If registered substance deviates from this rule, scientifically substantiated reason must be given in the 'Justification for deviations' field | • For a multi-constituent substance, impurities expected to be present in each reported composition as a maximum at 10% (concentration range and/or typical concentration)<br>• If registered substance deviates from this rule, scientifically substantiated reason must be given in the 'Justification for deviations' field |

*Guidance for identification and naming of substances under REACH and CLP: http://echa.europa.eu/guidance-documents/guidance-on-reach

# Substance identification

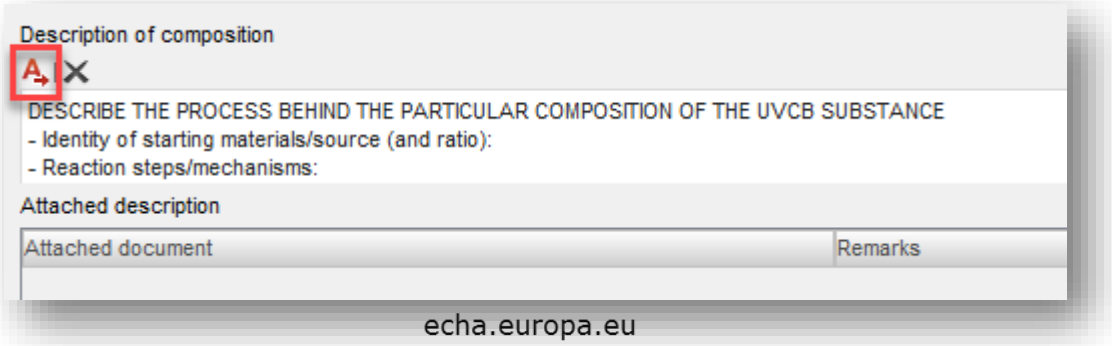
Composition of UVCB substance

- Composition must be provided
- Constituents for each reported composition must be provided in IUCLID section 1.2. under 'Constituents':
  - All individual constituents present at >10%, or relevant for classification and labelling 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 scientifically fully substantiated justification under 'Justification for deviations'

# Substance identification

Manufacturing process description of UVCB substance

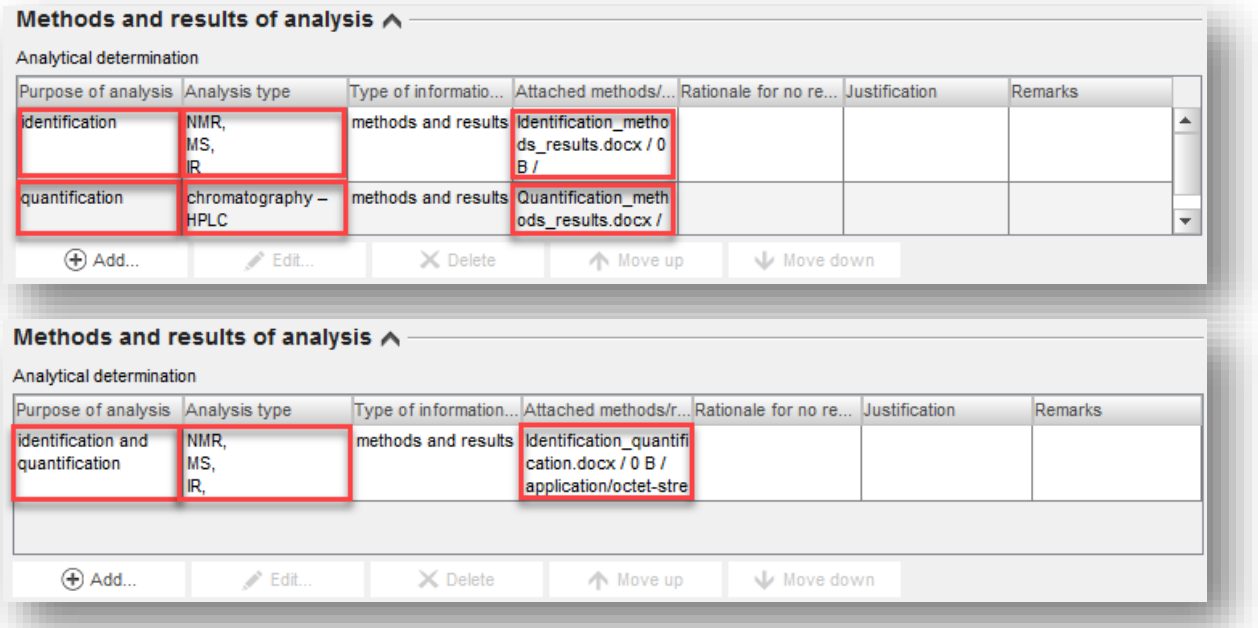
- Description of the source used and the process applied must be included in the 'Description of composition' field in IUCLID section 1.2.
- Read Q&A 1199
- Use free text template of IUCLID field marked with "A" to help you report relevant information
  - You must fill in the relevant data for your substance; inserting the template alone will not be considered complete



# Substance identification

Analytical information

- For your dossier to be considered complete in terms of analytical information, required analytical reports for identification and quantification must be attached in IUCLID section 1.4.



**Methods and results of analysis**

Analytical determination

| Purpose of analysis | Analysis type | Type of informatio... | Attached methods/... | Rationale for no re... | Justification | Remarks |
|---|---|---|---|---|---|---|
| identification | NMR, MS, IR | methods and results | Identification_methods_results.docx / 0 B / | | | |
| quantification | chromatography – HPLC | methods and results | Quantification_methods_results.docx / | | | |

Add... Edit... Delete Move up Move down

**Methods and results of analysis**

Analytical determination

| Purpose of analysis | Analysis type | Type of information... | Attached methods/r... | Rationale for no re... | Justification | Remarks |
|---|---|---|---|---|---|---|
| identification and quantification | NMR, MS, IR, | methods and results | Identification_quantification.docx / 0 B / application/octet-stre | | | |

Add... Edit... Delete Move up Move down

**As separate reports**

**In the same report**

# Justification for data waiving

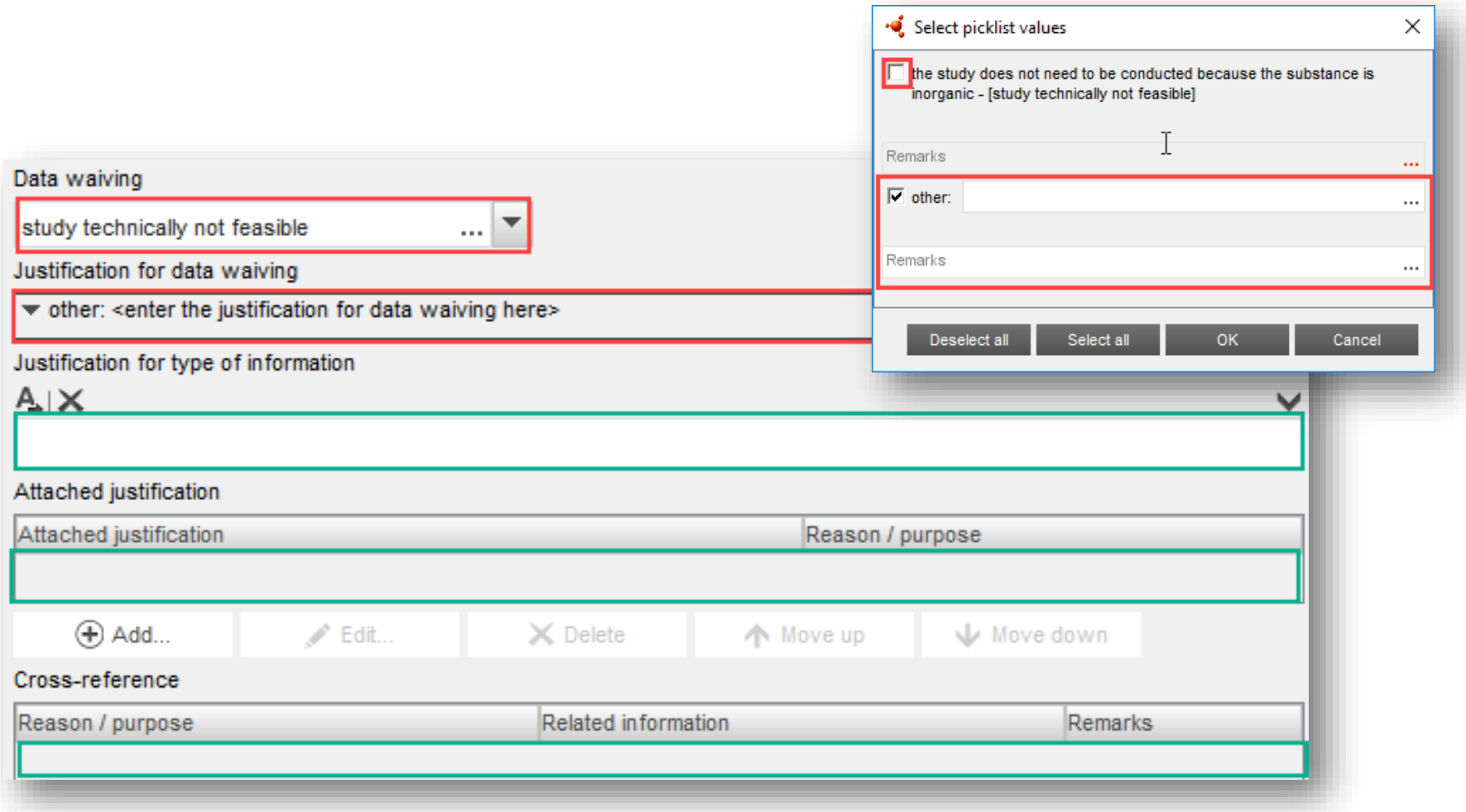
Four options available to fulfil REACH information requirements under Annex VII-XI (IUCLID sections 4–7):

1. Provide standard required study
2. Adaptation according to section 1 of REACH Annex XI:
   - Use of existing data, weight of evidence, (Q)SAR, in vitro methods, grouping of substances and read-across
   - If you utilise one of the above options, provide the relevant study results marked as a key study or weight of evidence
3. Provide a testing proposal
   - For Annex IX and X information
4. Provide a data waiving in accordance with Column 2 of REACH Annexes VII – X, or Annex XI sections 2 and 3

# Justification for data waiving

- Enter 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 scientifically substantiated justification in line with appropriate REACH Annex (examples to follow)
  - 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 ’Cross-reference’ field

# Justification for data waiving



# Justification for data waiving

- 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'."

# Justification for data waiving

- Examples of incomplete / complete justifications for data waiving

  Growth inhibition study to aquatic plants (REACH Annex VII, 9.1.2)

  "It is expected that aquatic plants will not be exposed to the substance."

  "The test does not need to be conducted as the substance is highly insoluble in water."

  Skin sensitisation (REACH Annex VII, 8.3)

  "According to REACH Annex XI section 2 it is technically not possible to conduct the study."

  "According to REACH Annex XI section 2 it is technically not possible to conduct the study because the substance is a gas."

# Justification for data waiving

- Examples of incomplete / complete justifications for data waiving

Adsorption/desorption (REACH Annex VIII, 9.3.1)

"The substance is a UVCB. Standard tests for this endpoint are intended for single substances and are not appropriate for this complex substance. Therefore the adsorption desorption behaviour of the test item could not be determined because of its complex nature. In addition, adsorption describes the covering of a solid surface by a thin film of a liquid or gas and the substance discussed here could not form such a thin film…"

"The test is not needed because all representative constituents of the UVCB substance have a low log Kow. See IUCLID section 4.7."

Acute toxicity oral (REACH Annex VII, 8.5.1)

"This substance is widely present in the environment, it can be found ubiquitously in the nature."

"Test not needed because an inhalation acute toxicity study is available in IUCLID section 7.2.2."

# Testing proposals on vertebrate animals

- Since September 2015, we proactively ensure that registrants have made an effort to consider potential availability of non-animal testing methods before proposing testing on vertebrate animals
- Registrants submitting new testing proposals concerning vertebrate animal tests need to provide their considerations of alternative methods in the registration dossier

# Testing proposals on vertebrate animals

- Considerations of alternatives must be provided in the field 'Justification for type of information' for each proposed vertebrate study to pass the completeness check
- You are strongly advised to use the text template provided in the IUCLID field and marked with "A". It lists elements necessary to be addressed when documenting your considerations

# Chemical safety report (CSR)

- A chemical safety report (CSR) must be provided, or a justification why a CSR is not required, must be included
  - 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

# Key points for completeness

- Be clear and transparent
- When providing a justification, always summarise main points of the justification in the expected field, and if needed, refer to a section/field where more details are given – note that reference alone is not enough
- Use correct field to provide information – we are not able to search the entire dossier:
  - Refer to manuals on our website and the integrated help system in IUCLID
  - Read manual checks document
  - In case your submission has failed technical completeness check, refer to the letter and carefully read through failure message in Annex 1

# Take-home points

- We are taking action to increase availability of relevant data through manual checks
- Scope of manual checks is **completeness**
- Read this document

# Common cases

# Overview

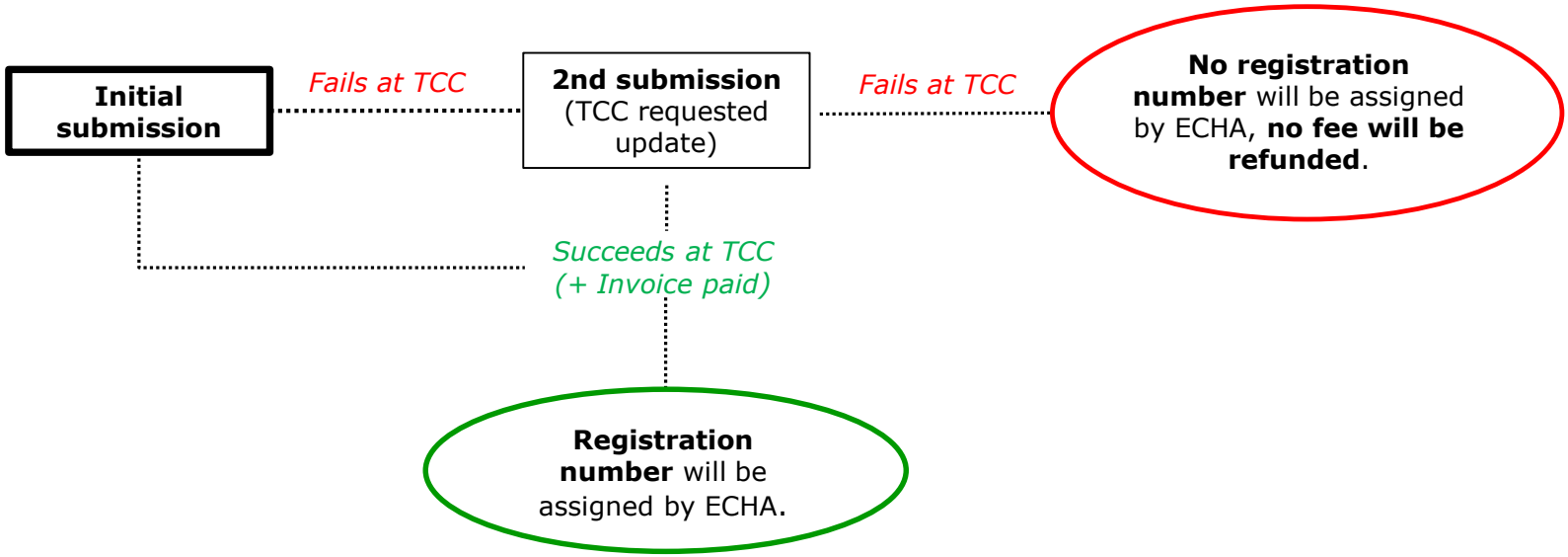
- **Case 1:** I failed technical completeness check for the second time. What are the consequences?
- **Case 2:** I failed technical completeness check the deadline is after another regulatory deadline. Which deadline do I follow?
- **Case 3:** I have an ECHA decision but my study for this endpoint is still ongoing. How should I report this in my dossier?
- **Case 4:** My previous submission was a dossier for a "notified new substance" (NONS) with no tonnage band upgrade. Now I will become the lead of a joint submission in the same tonnage band. Can I still rely on the NONS derogation?

# Case 1

I failed the technical completeness check for the second time. What are the consequences?

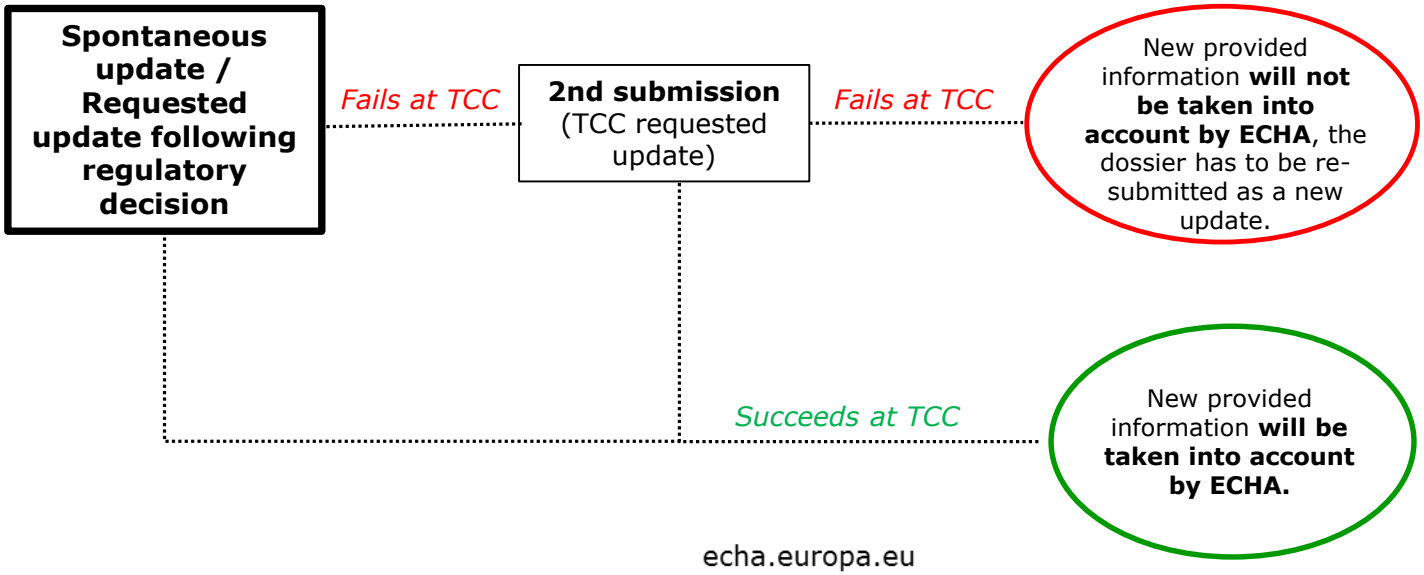
# Case 1

- Initial submission fails technical completeness check for the second time:
  - Second failure leads to rejection of submission
  - No registration number will be assigned to your substance
  - Related fees are not refunded



# Case 1

- Update of existing registration fails second technical completeness check:
  - Second failure leads to rejection of submission
  - New information is not accepted
  - You keep your registration number



# Case 2

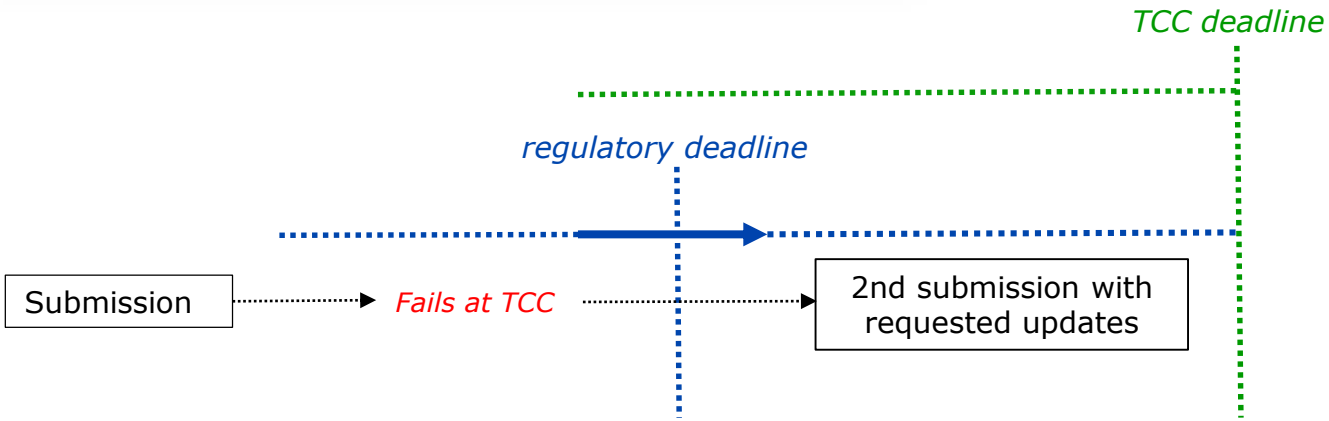
I failed technical completeness check and the deadline is after another regulatory deadline. Which deadline do I follow?

# Case 2

**Advice and further observations**

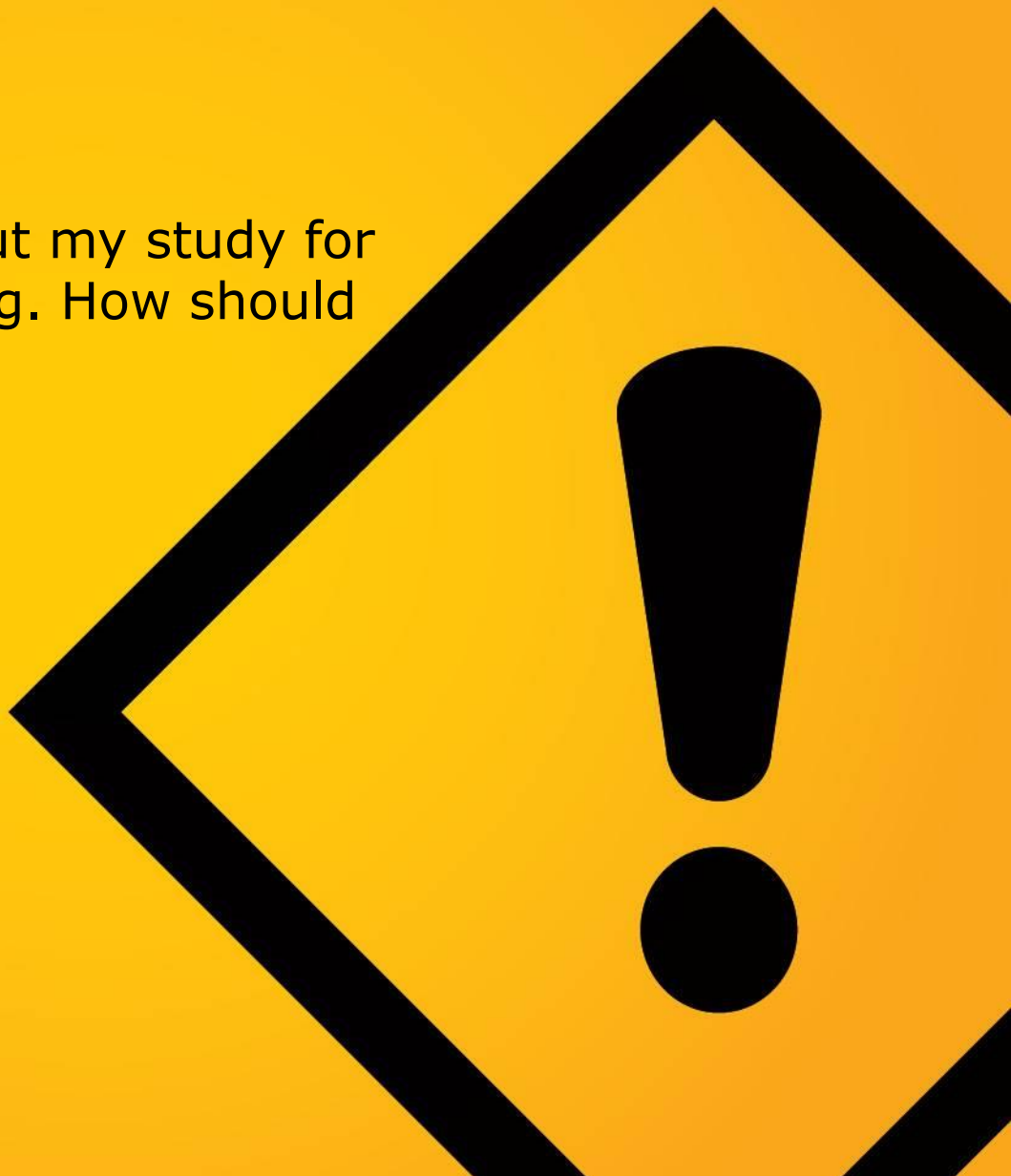
If the update of your registration was required by a decision on evaluation, the present letter and the completeness of your update within the meaning of Article 20(2) REACH have no bearing on your obligations under the decision on evaluation. However, you will fail to comply with the decision on evaluation, if you do not submit all of the information required therein by the abovementioned technical completeness check deadline or by the deadline indicated in that decision, whichever is later.

We will not continue with the evaluation before you submit the update requested by the technical completeness check or before the technical completeness check deadline



# Case 3

I have an ECHA decision but my study for this endpoint is still ongoing. How should I report this in my dossier?



# Case 3

- Applies to compliance check (CCH), testing proposal evaluation (TPE) and substance evaluation (SEV) decisions
- Data waiver – select “other” and insert: “This information will be submitted later based on ECHA decision number TPE/SEV/CCH-D-xxxxxxxxxx-xx-xx”
- If appropriate decision number is not included, we cannot accept an ”ongoing study” as a data waiving justification
- Update as soon as study results are available.
- Update other impacted sections in IUCLID as relevant (classification and labelling, PBT assessment, chemical safety report)

# Case 4

My previous submission was a dossier for “notified new substance” (NONS) with no tonnage band upgrade. Now I will become the lead of a joint submission in the same tonnage band. Can I still rely on the NONS derogation?

# Case 4

- A NONS (Notified New Substance) is a substance notified under the previous Directive 67/548/EEC
- NONS substances considered registered under REACH
- Limited completeness check applies when NONS registration is updated without changes to information requirements

# Case 4

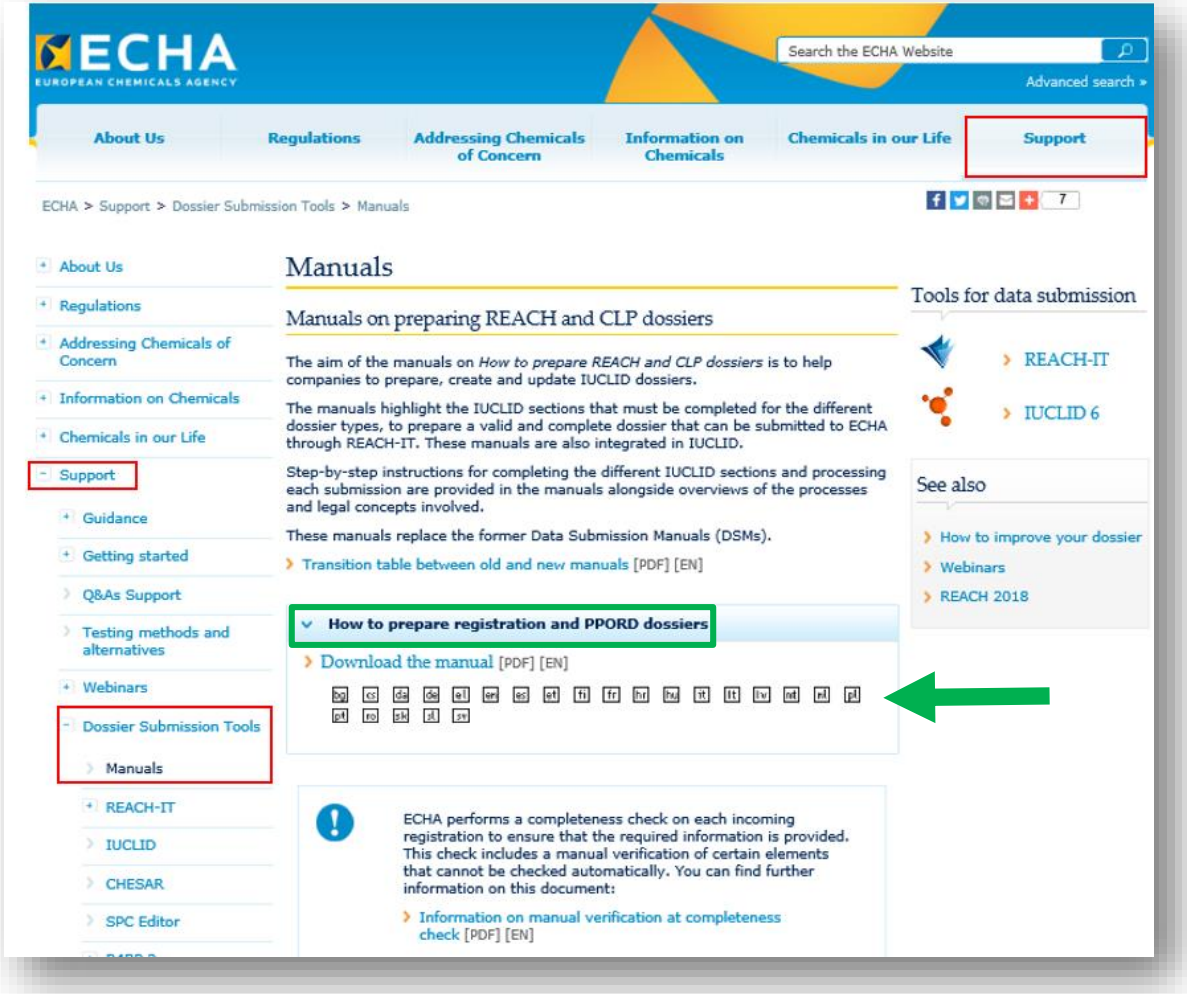
- When becoming a lead of a joint submission, the dossier becomes the reference point of the joint submission and a **full completeness check** is applied
- NONS derogation no longer valid
- Submitted dossier needs to pass enhanced completeness check, including manual checks

# Case 4

- Data migrated from old formats (SNIF, IUCLID 4) may appear incomplete; however all required fields have to be filled in
  - Same applies to cases with permission to refer to study information older than 12 years: failures identified when running the Validation assistant have to be fixed
- See Annex 4 of the manual: How to prepare registration and PPORD dossiers

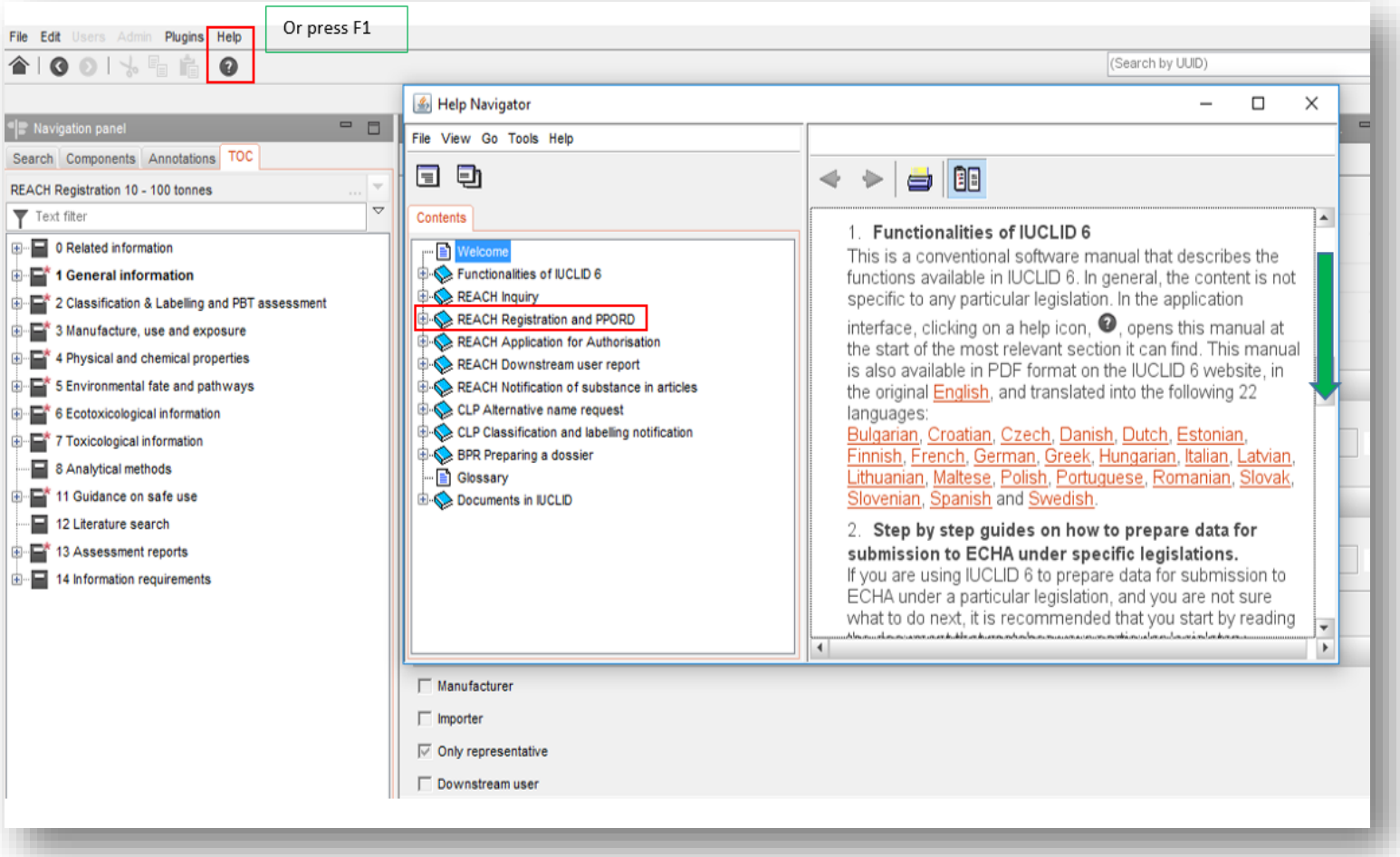
# Support

# Registration manual

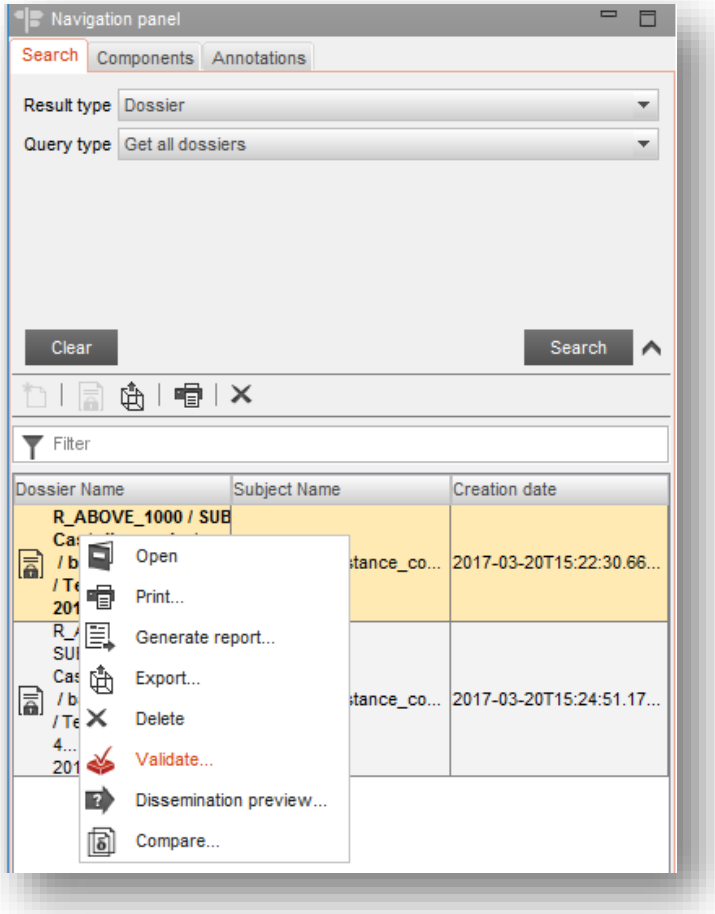


# Information on manual checks

# Registration manual: IUCLID

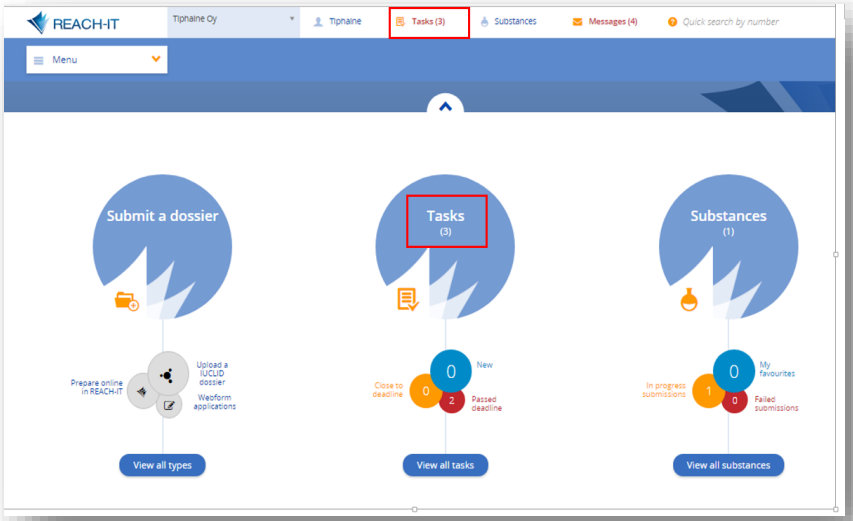


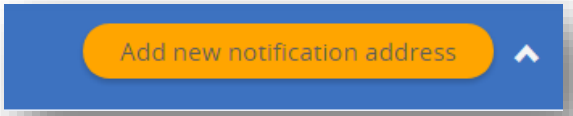
# Validation assistant: IUCLID




Run the Validation assistant before and after creating your dossier

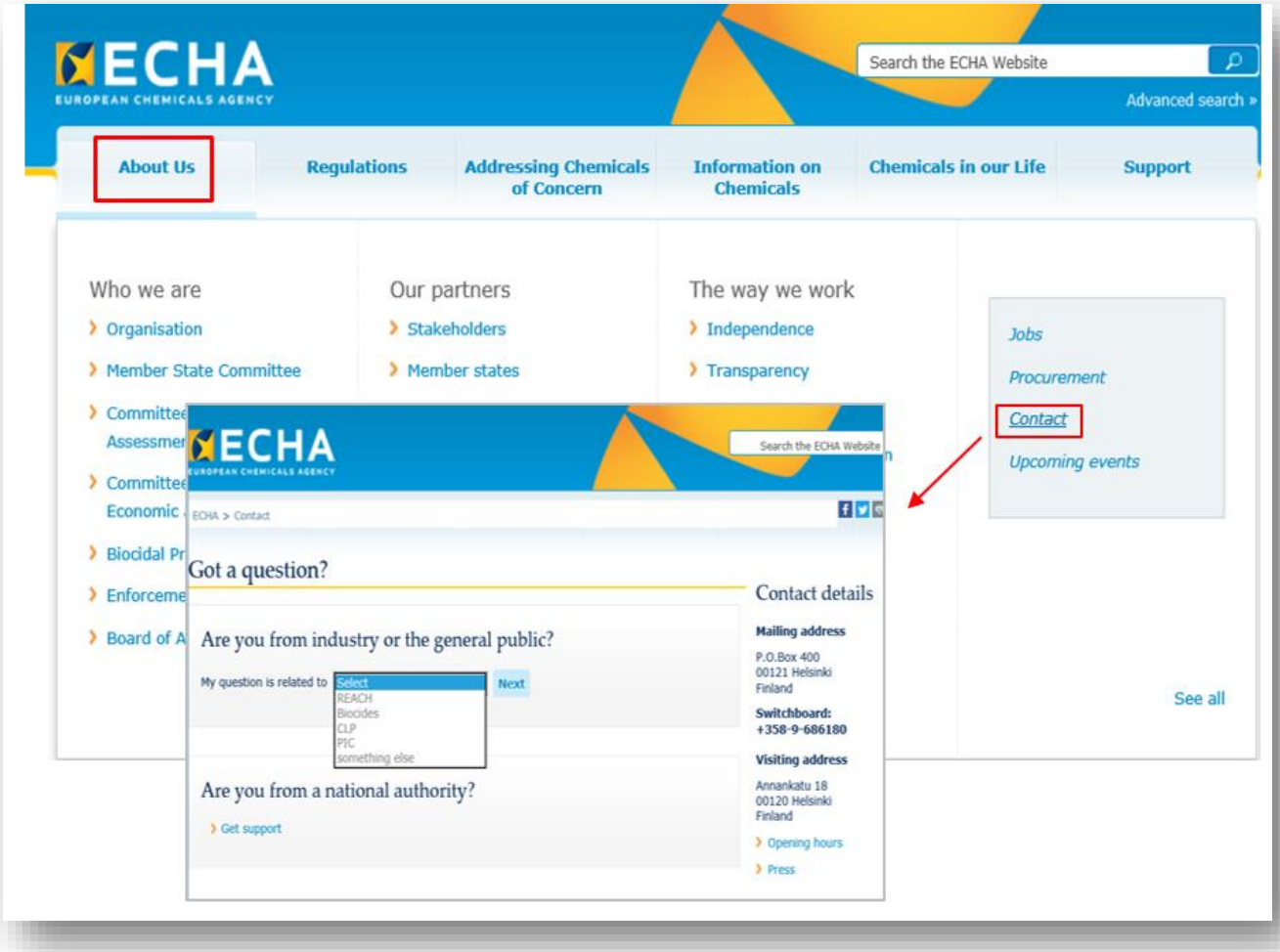
# Technical completeness check letter



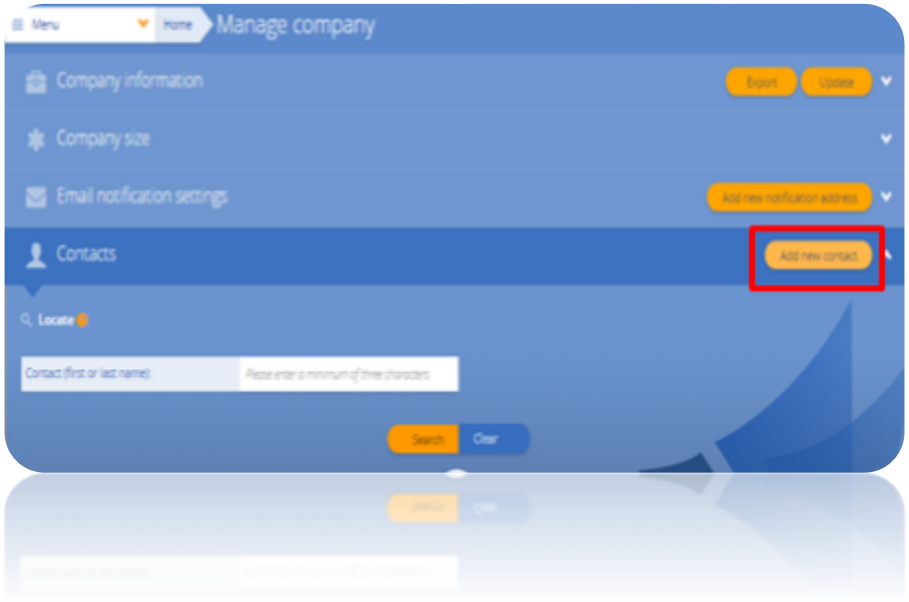




- In case of failure, technical completeness check letter available under your 'tasks' in REACH-IT
- Make sure to assign a relevant email address under 'email notification settings' so that an email notification from REACH-IT is sent to the right person

# Contact form



# Additional support




- Assign a **relevant** contact person in REACH-IT:
  - Make sure the contact is the **person responsible for the submission**
  - Person can be contacted by us via phone/email

# Additional support

- We may contact you by phone:
  - To remind you that the technical completeness check deadline is approaching
  - To assist you with complex failures
- A summary email is always sent after the call

**We are here to help you!**

# Available support

- Registration manual
- Manual verification document
- Validation assistant
- Technical completeness check letter
- Contact form
- Additional support

# Conclusions

# Conclusions

- Always use the Validation assistant before submitting your dossier; never submit a dossier with submission check failures
- More information on manual verification at the completeness check step, read this document
- Monitor your REACH-IT tasks and messages regularly
- If you need help, contact us: echa.europa.eu/contact

# Questions and answers

# Thank you!

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