

REACH 2018

webinars

Completeness check Process

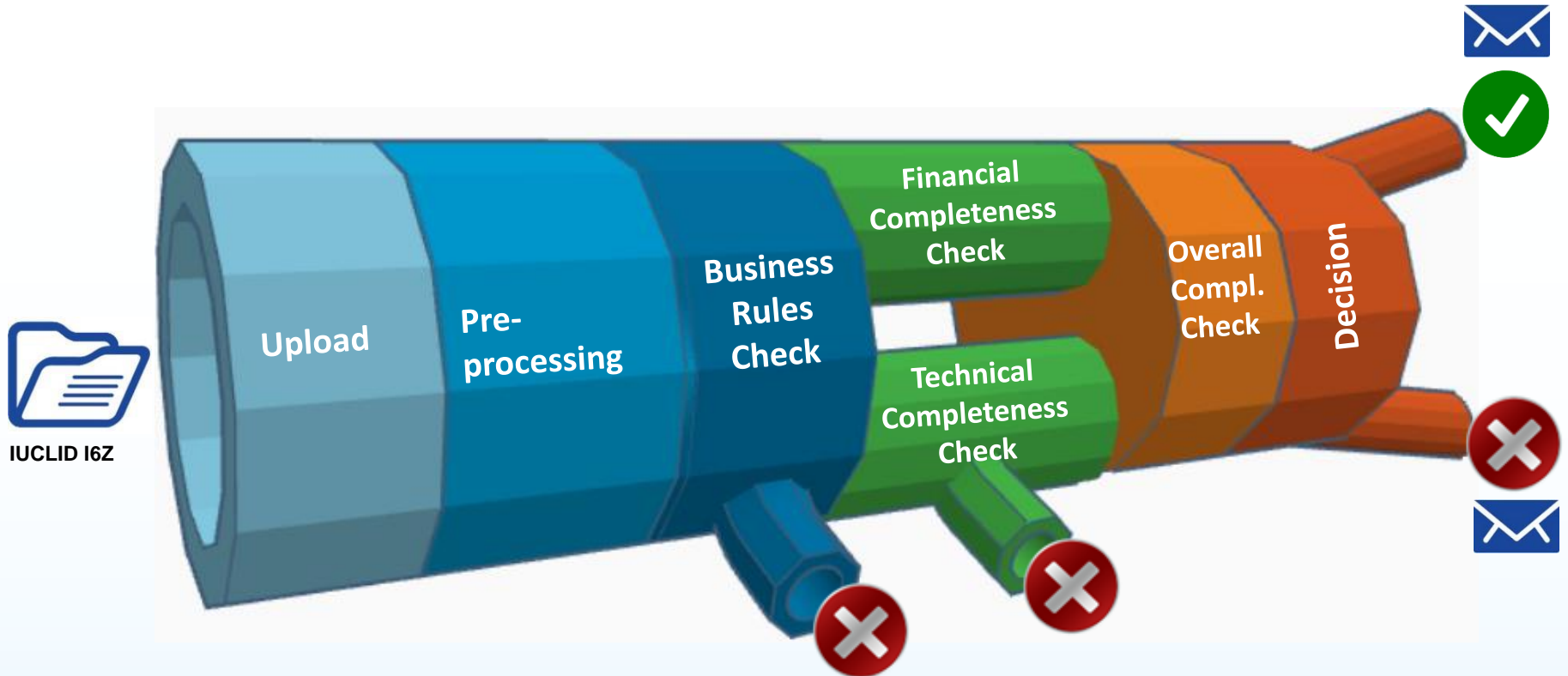
15 March 2018

11.00 – 12.00 Helsinki time

Mariia Aleksanian, ECHA



Submission process



Submission process in REACH-IT

Completeness check

- Ensures all required elements are in the registration dossier as per Article 20(2)
- Performed on each registration dossier submitted to us
 - initial and update submissions

Completeness check

Background

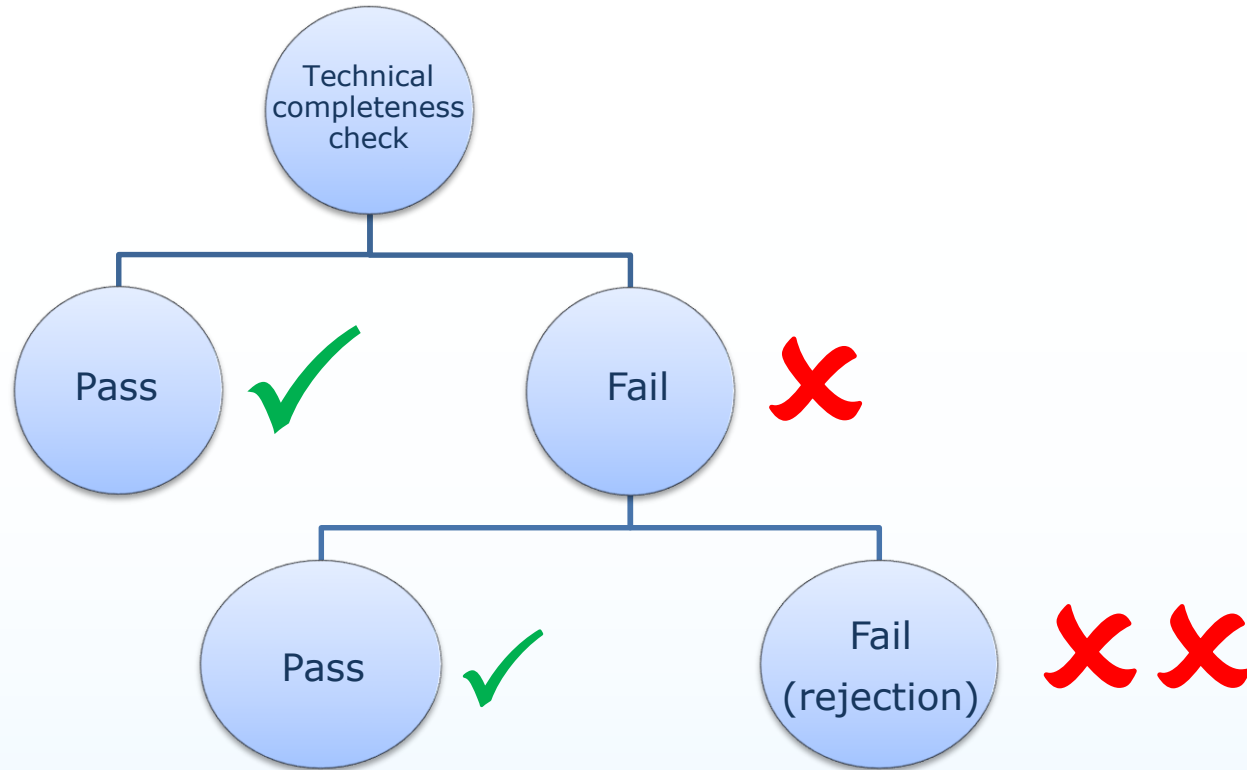
- 2010: REACH information requirements converted into automated completeness check rules
- 21 June 2016: enhanced completeness check enters into force: revised automated rules and additional manual checks performed by us
 - Manual checks: completeness check step takes slightly longer than before
 - If you plan to update your registration and the previous dossier was submitted using IUCLID 5, you may need to revise data before submitting in IUCLID 6



Reserve time

Completeness check

Outcomes



Completeness check

Positive outcome

Technical completeness check passes



- Message in REACH-IT
- If payment following an invoice is received on time, your submission is complete and a positive decision is sent via REACH-IT
- Initial submission: registration number assigned
- Update of existing registration: We accept the updated information in the database

Completeness check

Negative outcome

First failure of technical completeness check



- Letter in 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

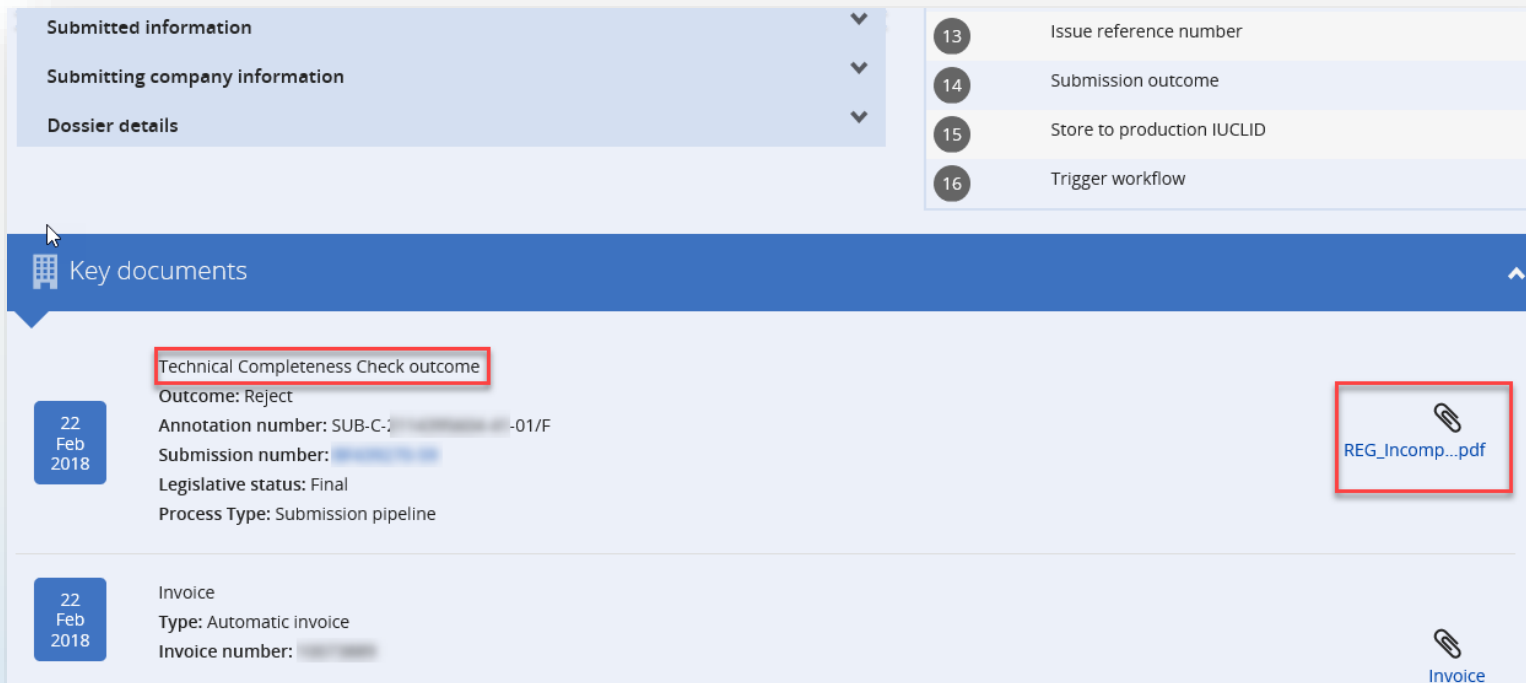
Completeness check

Negative outcome

- Second failure of technical completeness check **XX**
- Negative decision in REACH-IT task box informing submission is rejected
 - Initial submission:
 - Registration number not granted
 - Fee not refunded
 - Update of existing registration:
 - Updated information not accepted into our database and subsequent processes
 - You keep your registration number
 - After rejection you can submit a new dossier

Technical completeness check Letter

- After first failure
- Found on submission page under key documents



Submitted information

Submitting company information

Dossier details

13 Issue reference number

14 Submission outcome

15 Store to production IUCLID

16 Trigger workflow

Key documents

22 Feb 2018

Technical Completeness Check outcome

Outcome: Reject

Annotation number: SUB-C-...-01/F

Submission number: ...

Legislative status: Final

Process Type: Submission pipeline

REG_Incomp...pdf

22 Feb 2018

Invoice

Type: Automatic invoice

Invoice number: ...

Invoice

Technical completeness check Letter

- Deadline to correct failures and re-submit your dossier
- Annex 1 with detailed information about incompleteness and instructions on correcting failures
- Annex 2 with instructions on creating updated dossier and validating it before submission in REACH-IT

Technical completeness check Letter

Deadline for correcting failures and submitting updated dossier

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 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 column 2 of Annexes VII to X, on sections 2 or 3 of Annex XI (testing technically not possible, substance-tailored exposure-driver testing) or on any other valid reason that is fully substantiated:
 - Select a relevant value from the picklist in the field 'Justification for data waiving'; or
 - Select 'other:' and insert a valid explanation for the data waiving in the adjacent free-text field; or
 - If you have already received an ECHA decision or a draft decision requesting you to carry out a test for this endpoint but the information is not yet available, select 'other' from the field 'Justification for data waiving' and type the following sentence in the adjacent text field: "This information will be submitted later based on ECHA communication/decision number TPE/CCH/SEV-x-xxxxxxxxxx-xx-xx/x".

Note that if the data waiving relies on other information (e.g. a test or a classification) this information must be included in the appropriate section of the dossier. This information is manually checked.

For further information, consult the supporting documents below on how to provide information on the information requirements in Annexes VII-XI under REACH:

[How to prepare registration and PPORD dossiers](#)

[Endpoint specific guidance R7a, R7b and R7c](#)

[Q&As on preparing registration dossiers in IUCLID](#)

Note: this failure was detected as part of the additional verifications by ECHA staff and therefore cannot be displayed by the Validation assistant tool.

Annex 1:

- Failing section and document name
- Failure description
- Instructions for corrections
- Reference to relevant support material
- Indication if the failure can be detected by the validation assistant

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 the information requested in Annex 1 of this communication, in the appropriate fields of IUCLID. To avoid introducing new completeness check failures in your update dossier, it is not advisable to update any other parts of the dossier at this stage, than those listed in Annex 1.

Indicate in the dossier header that 'The submission is an update' and enter the submission number **XX000000-00** in the field 'Last submission number'. 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'.

2. Use the Validation assistant

Use the Validation assistant available in IUCLID in order to minimise the risk for failures and rejection. Validate your substance dataset and correct any failures reported at this level before creating the dossier. Validate also the final dossier before exporting it, and address any issues identified. Any failure in the Validation assistant Submission checks tab that is left uncorrected will lead to the rejection of your submission.

In order to run the Validation assistant on the IUCLID desktop or server application, right-click on your substance dataset or dossier and select 'Validate'.

The technical completeness check performed by ECHA includes additional manual verifications. These manual verifications cannot be replicated by the Validation assistant. Therefore, the related failures cannot be displayed by the Validation assistant report.

Annex 2:

- Instructions for submitting a dossier in response to the letter
- Reminder to use the validation assistant

Use correct submission and communication numbers to avoid failing the business rules step

Technical completeness check

Letter summary

- Carefully read failure descriptions in Annex 1 and follow instructions on how to correct them
- Correct all failures listed in the letter before submitting an update
- Only correct sections addressed in Annex 1 of the letter
- Contact us before the technical completeness check deadline if unsure about failures:
echa.europa.eu/contact

Take home messages

- Technical completeness check is performed on both initial and update submissions and includes automatic and manual checks on your dossier
- In case of first failure, you receive a letter to your task box in REACH-IT. Make sure you correct all failures listed in the letter before submitting an update
- Use our contact form for questions or uncertainty on correcting the failures:
echa.europa.eu/contact