

Overview of the technical completeness check process

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Technical Completeness Check



1. Introduction
2. Information requirements
3. TCC process

Technical Completeness Check



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1. Introduction



1. Introduction



- Completeness check carried out according to Article 20:

*“The Agency shall undertake a completeness check of each registration in order to ascertain that **all the elements required** [...], as well as the **registration fee** [...] have been provided.”*

Completeness check =	Technical Completeness Check (TCC)
	+
	Payment received in full

Technical Completeness Check



1. Introduction
- 2. Information requirements**
3. TCC process

2. Information requirements

Annexes of REACH describe the requirements

Annex VI: Identity of registrant, Identity of substance, C&L, Information about uses, Guidance on safe use ...

Annexes VII to X: Physicochemical, toxicological and ecotoxicological studies depend on tonnage:

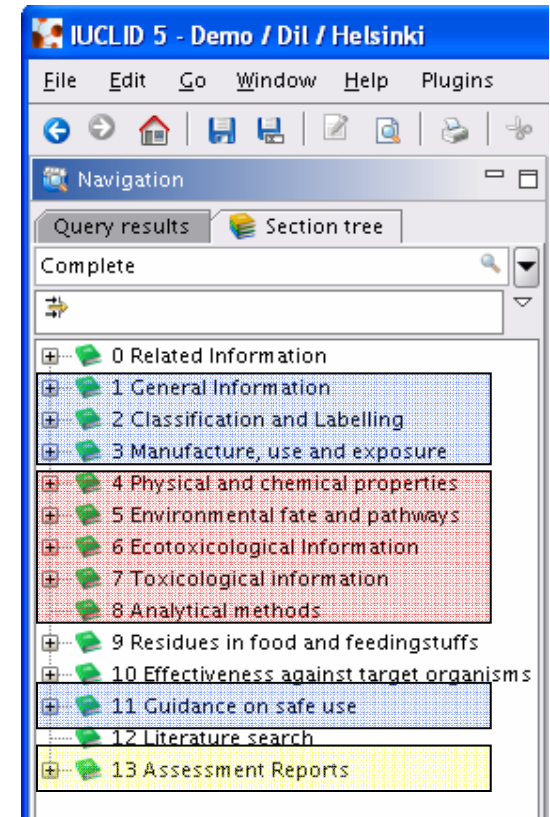
1-10T: Annex VII

10-100T: Annex VII + VIII

100-1000T: Annex VII + VIII + IX

>1000T: Annex VII + VIII + IX + X

Chemical Safety Report: only for dossiers > 10T



2. Information requirements



Requirements for LEAD dossier vs. MEMBER dossier

Lead dossier

- All the requirements for the highest tonnage band within the joint submission.

Member dossier

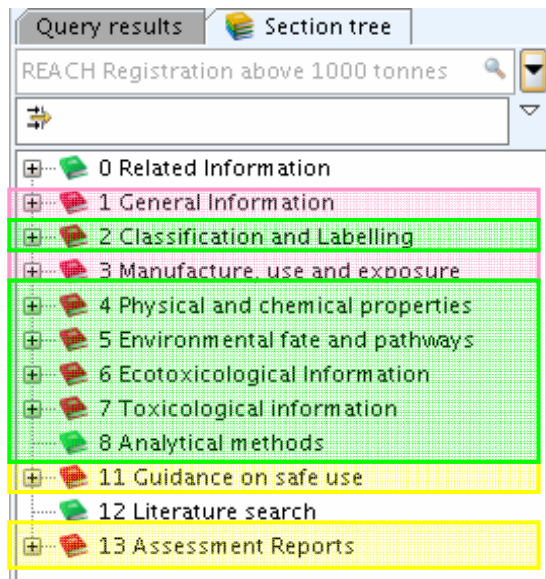
- Only limited information needed: identification of company and substance and information on manufacture and uses.
- Any other information included in the dossier will be regarded as an opt-out.

2. Information requirements

Private data submitted by the
LEAD and the MEMBER

Data submitted only by the
LEAD (if not opted-out)

LEAD Dossier



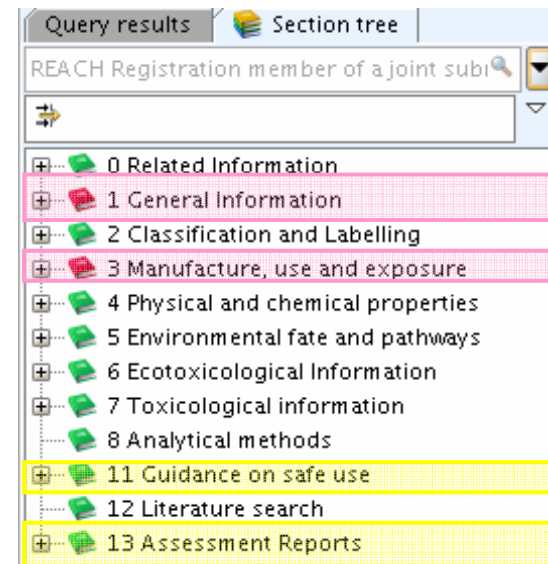
Query results | Section tree

REACH Registration above 1000 tonnes

- 0 Related Information
- 1 General Information
- 2 Classification and Labelling
- 3 Manufacture, use and exposure
- 4 Physical and chemical properties
- 5 Environmental fate and pathways
- 6 Ecotoxicological Information
- 7 Toxicological information
- 8 Analytical methods
- 11 Guidance on safe use
- 12 Literature search
- 13 Assessment Reports

Data submitted either by the
LEAD or individually

MEMBER Dossier



Query results | Section tree

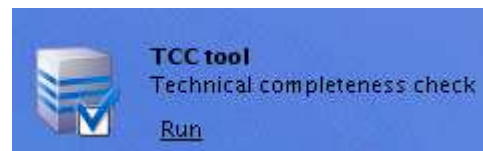
REACH Registration member of a joint sub...

- 0 Related Information
- 1 General Information
- 2 Classification and Labelling
- 3 Manufacture, use and exposure
- 4 Physical and chemical properties
- 5 Environmental fate and pathways
- 6 Ecotoxicological Information
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- 11 Guidance on safe use
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2. Information requirements

Technical Completeness Check (TCC)

- Detailed instructions on the required information in a dossier are given in 'Dossier Submission Manual 5: How to Complete a Technical Dossier for Registrations and PPORD notifications'.
- Technical Completeness Check tool

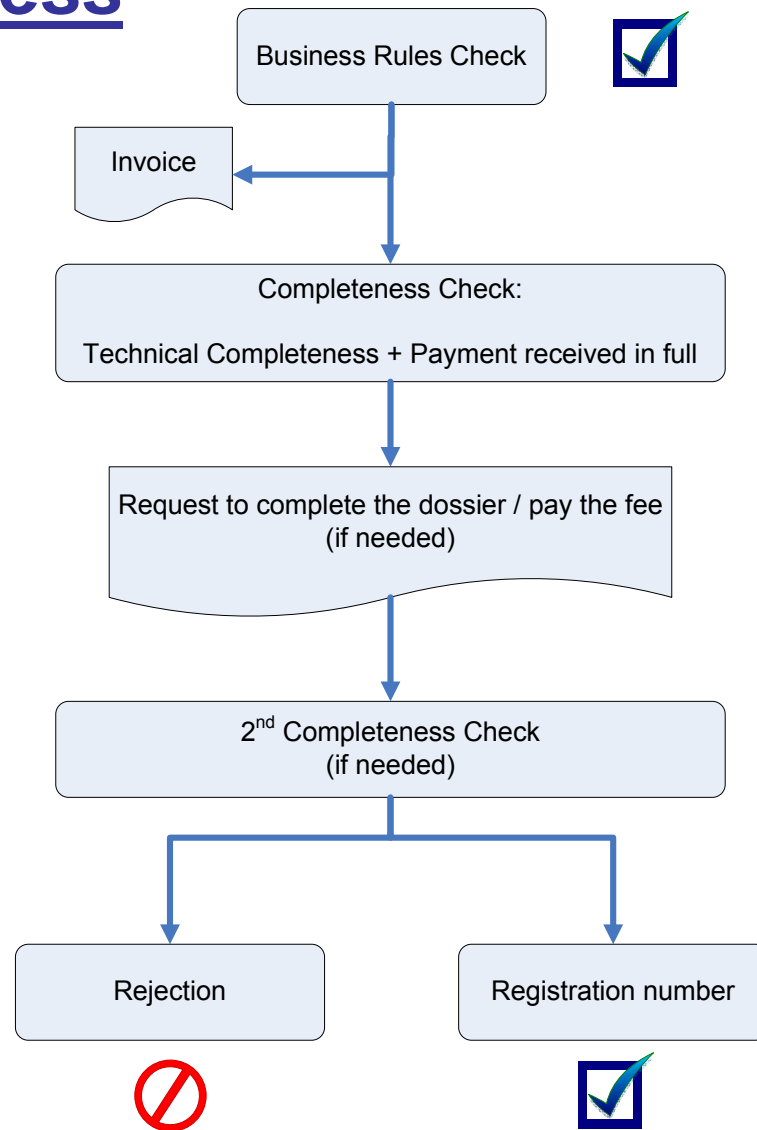


Technical Completeness Check

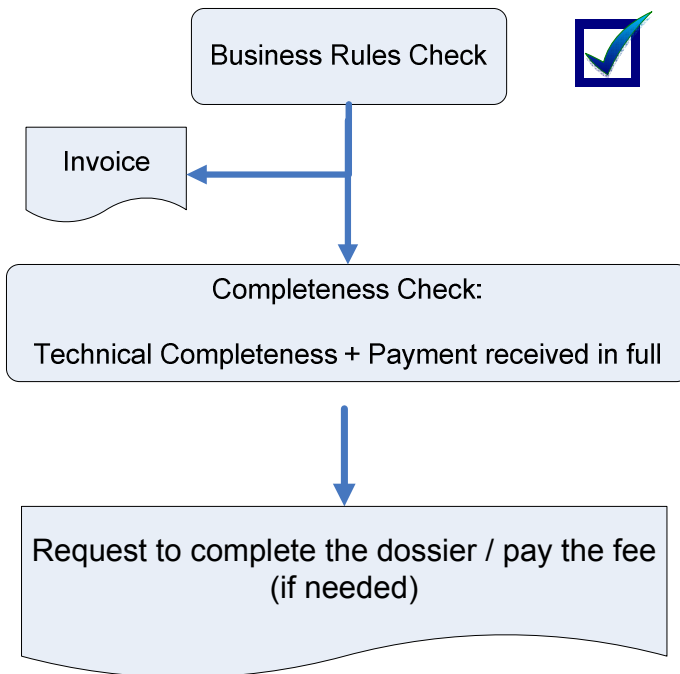


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3. TCC process



3. TCC process



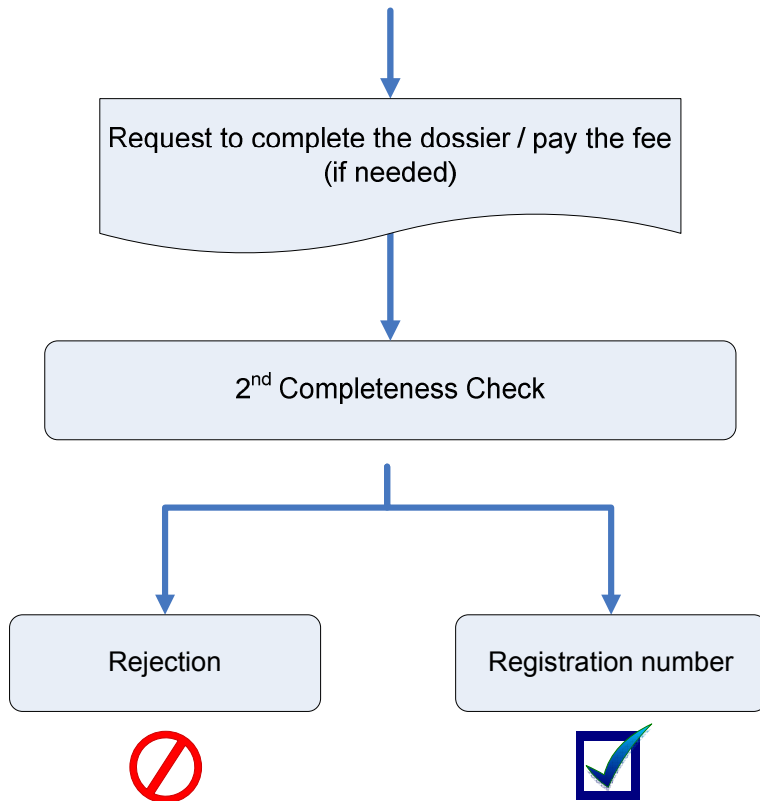
Completeness check result:

- Within **three weeks** of the submission date
- Exception: if dossier submitted during the last two months before the relevant deadline for registration of phase-in substances, the completeness check will take place within **three months** of that deadline

If the dossier is considered incomplete:

- ECHA sends a request for further information and provides you with a detailed list of the information that is missing.
- You are also informed whether the payment has been received or not.
- ECHA sets a deadline to resubmit a complete dossier.

3. TCC process



In case ECHA requests further information:

- Once the dossier is resubmitted, ECHA will perform a second completeness check.

- If your dossier is considered complete, you will receive the registration number.
- If your dossier is again considered incomplete, your registration will be rejected.

Useful links



European Chemicals Agency

- HOME
- SIEF
- REACH
- CONSULTATIONS
- ECHA CHEM
- REACH-IT
- CLP
- GUIDANCE
- LEGISLATION
- HELP
 - FAQ's
 - Documents**
 - National Helpdesks
 - ECHA helpdesk
- PRESS AND EVENTS
- ABOUT ECHA

Overview of Documents

[REACH-IT](#)

[Inquiry](#)

[PPORD](#)

[Registration](#)

Processes

Data Submission Manual 4: [How to submit a valid dossier to ECHA and complete the dossier header](#) (📄)

Data Submission Manual 5: [How to complete a technical dossier for registrations and PPORD notifications](#) (📄)

Data Submission Manual 8: [Business Rules validation](#) (📄)

[IUCLID 5 End User Manual vol. 1](#)

[IUCLID 5 End User Manual vol. 2](#)

[CSR User Manual](#)

[How to report identified uses in IUCLID 5](#) (📄)

Industry User Manual Part 1: [Getting started with REACH-IT](#) (📄)

[Data management](#) (📄)

[e Box](#) (📄)

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Download

Stand-alone version 5.1.1

Distributed version 5.1.1

TCC plugin

Key messages

- TCC is performed only once the business rules step has been fulfilled.
- Lead dossier must include all information required for the highest tonnage band of the joint submission.
- Member dossier only needs basic information.
- Use the TCC plug-in to check your dossier for completeness before submitting it to ECHA.
- Consult the relevant manuals for details on the minimum requirements to create a complete dossier.

Thank You
for your attention

