

Technical Completeness Check

Lead Registrant Webinar
22th November 2012

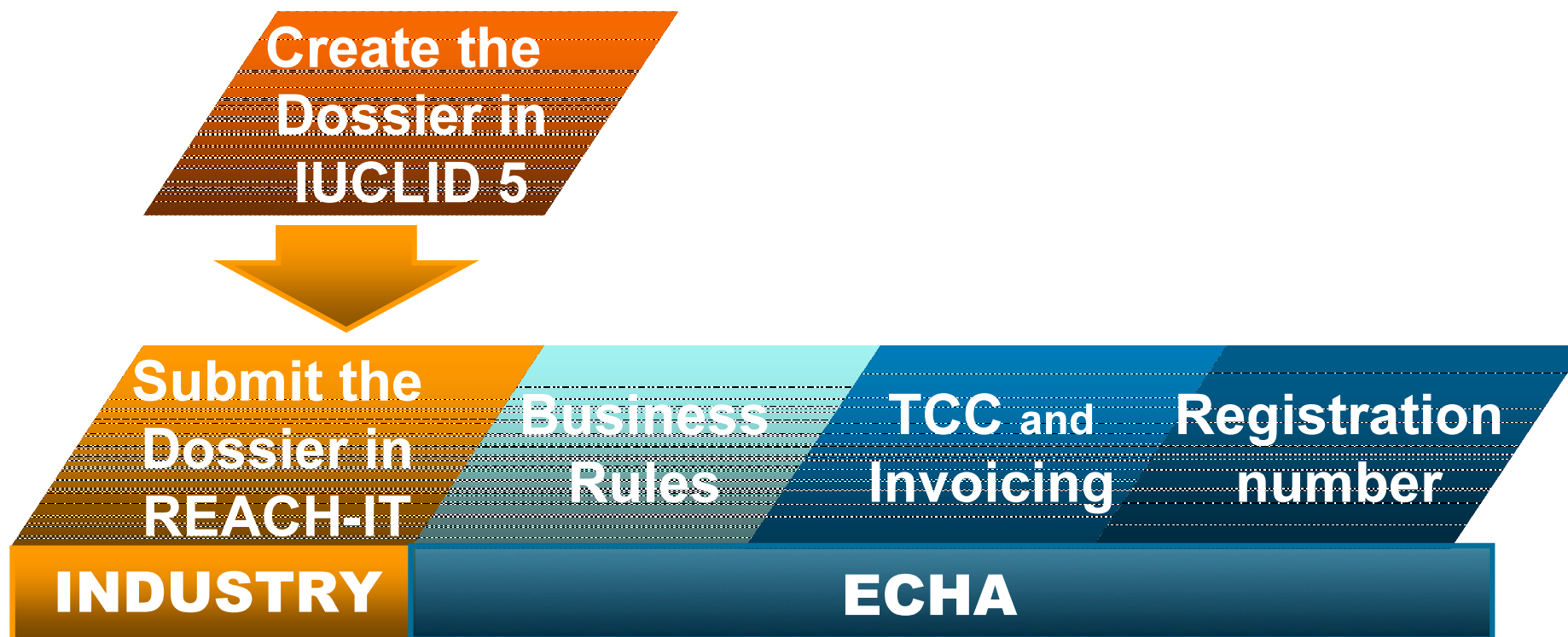
Terhi Rantala
Dossier Submission and Dissemination Unit

Agenda

- **Introduction**
- Information requirements
- TCC process
- Useful links
- Key messages



Pipeline



Introduction

Completeness Check is performed in accordance with Article 20(2) of the REACH Regulation

Completeness Check = **Technical Completeness Check** **+** **Financial Completeness Check**

- ECHA examines that all the necessary fields in IUCLID 5 dossier have been filled
- No assessment of the information at this stage

'Complete' does not mean 'Compliant'

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Information requirements

REACH annexes

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:

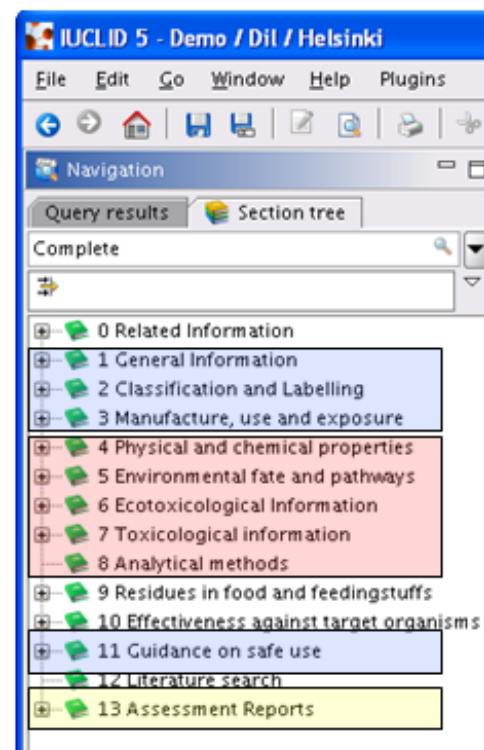
1-10T: Annex VII

10-100T: Annex VII + VIII

100-1000T: Annex VII + VIII + IX

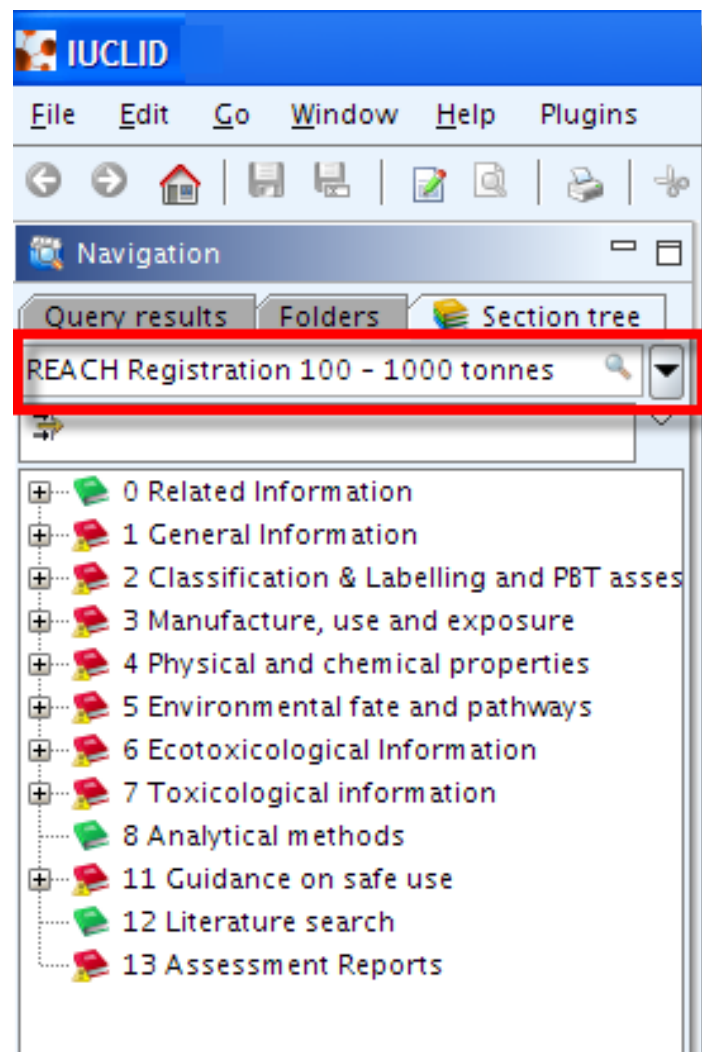
>1000T: Annex VII + VIII + IX + X

Chemical Safety Report: only for dossiers > 10T



Information requirements

IUCLID 5 view mode



Information requirements

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 information on the manufacture and uses
- Any other information included in the dossier will be regarded as an opt-out

Information requirements

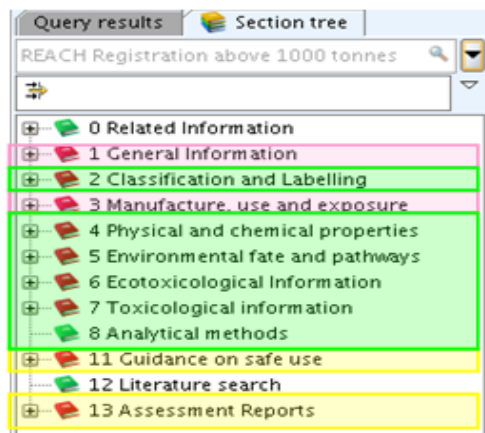
Requirements for LEAD dossier vs. MEMBER dossier

Private data submitted by the LEAD and the MEMBER

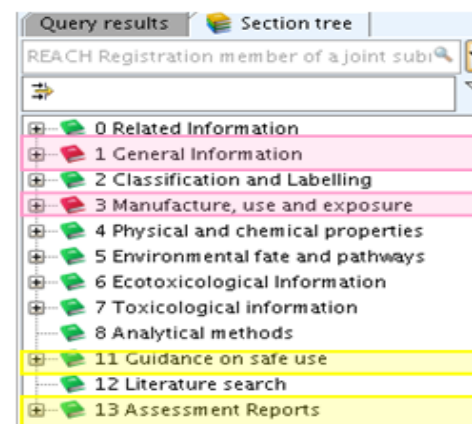
Data submitted only by the LEAD (if not opted-out)

Data submitted either by the LEAD or individually

LEAD Dossier



MEMBER Dossier

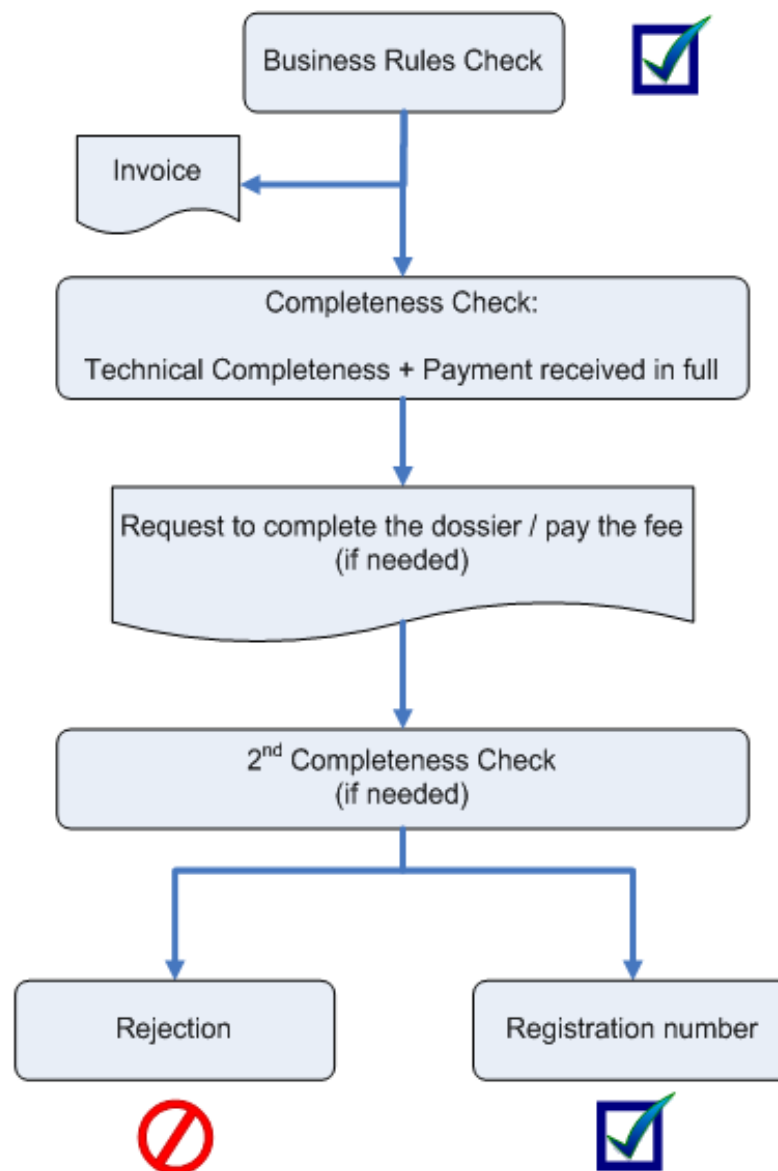


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TCC process



TCC Process - TCC passed

If you have passed the Technical Completeness Check
and
you have paid the fee by the due date
then
you will receive a decision confirming your successful registration

TCC Process - TCC failed

You get a letter to your REACH-IT mailbox including:

- The deadline for resubmission (120 days for registration dossiers)
- The list of missing information
- The instructions on how to proceed
- The links to all the relevant support

TCC Process - TCC failed

How to update your dossier?



22 November 2012

CompanyName

Street
PostalCode, Town
Country

Submission date: DD Month YYYY

Submission number: AA111111-11

Communication number: SUB-C-1111111111-11-11/F

FURTHER INFORMATION REQUIRED ON YOUR REGISTRATION REGULATION (EC) NO 1907/2006

Dear Sir/Madam,

In accordance with Article 20(2) of Regulation (EC) No 1907/2006 ("the Regulation"), the European Chemicals Agency (ECHA) has examined your registration dossier for **SubstanceName** by **CompanyName**.

The registration was considered incomplete, because not all the information required by the REACH Regulation were available. For the details on the incomplete registration, please refer to the report in Annex 1 of this letter.

Dossier creation wizard

Enter additional administrative information concerning your dossier
Dossier template: REACH Registration 100 - 1000 tonnes

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 lead registrant

Tonnage band: Between 100 to 1000 tonnes/year
On-site isolated intermediates tonnage band (REACH Article 17):
Transported isolated intermediates tonnage band (REACH Article 18):

Specific submissions

The submission is an update
Last submission number: AA111111-11
Reason for updating
 Further to a request/decision from regulatory body
 Spontaneous update

Dossier specific information

V1170: The phase-in status is mandatory. (DossierRecreationInfo.phaseinstatus)

1 2 3 4 5 6 7 8

< Back Next > Finish Cancel

TCC Process - TCC failed

How to update your dossier?



22 November 2012

CompanyName
Street
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Country

Submission date: DD Month YYYY

Submission number: AA111111-11

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Required Action

Based on the above, you are required to submit all the information required to update your first submission by the technical completeness...

Dossier creation wizard

Enter additional administrative information concerning your dossier
Dossier template: REACH Registration 100 - 1000 tonnes

On-site isolated intermediates tonnage band (REACH Article 17) []

Transported isolated intermediates tonnage band (REACH Article 18) []

Specific submissions

The submission is an update

Last submission number: AA111111-11

Reason for updating

Further to a request/decision from regulatory body

Number: SUB-C-1111111111-11-11/F

Remarks: []

Spontaneous update

Dossier specific information

Phase-in

Phase-in Non phase-in

Reviewed by an assessor

Message: V1170: The phase-in status is mandatory. (DossierRecreationInfo:phaseinstatus)

1 2 3 4 5 6 7 8
Enter administrative information

< Back Next > Finish Cancel

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- Conclusion



Useful links

- Data Submission Manual Part 05 - How to complete a technical dossier for registrations and PPORD notifications
<http://echa.europa.eu/web/guest/support/dossier-submission-tools/>
- IUCLID 5 website (TCC plug-in)
<http://iuclid.echa.europa.eu/>
- ECHA Helpdesk
<http://echa.europa.eu/web/guest/contact>

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Key messages

- All the relevant available data should be inserted in your IUCLID 5 dossier
- Lead dossier must include all the information required for the highest tonnage band of the joint submission
- Second TCC failure leads to the rejection of the dossier. Related fees are not refunded
- Run the TCC plug-in on the final dossier prior to submitting it in REACH-IT

Thank You!