

# Important steps after dossier submission

Lead Registrant Webinar  
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# Agenda

**Technical Completeness Check**

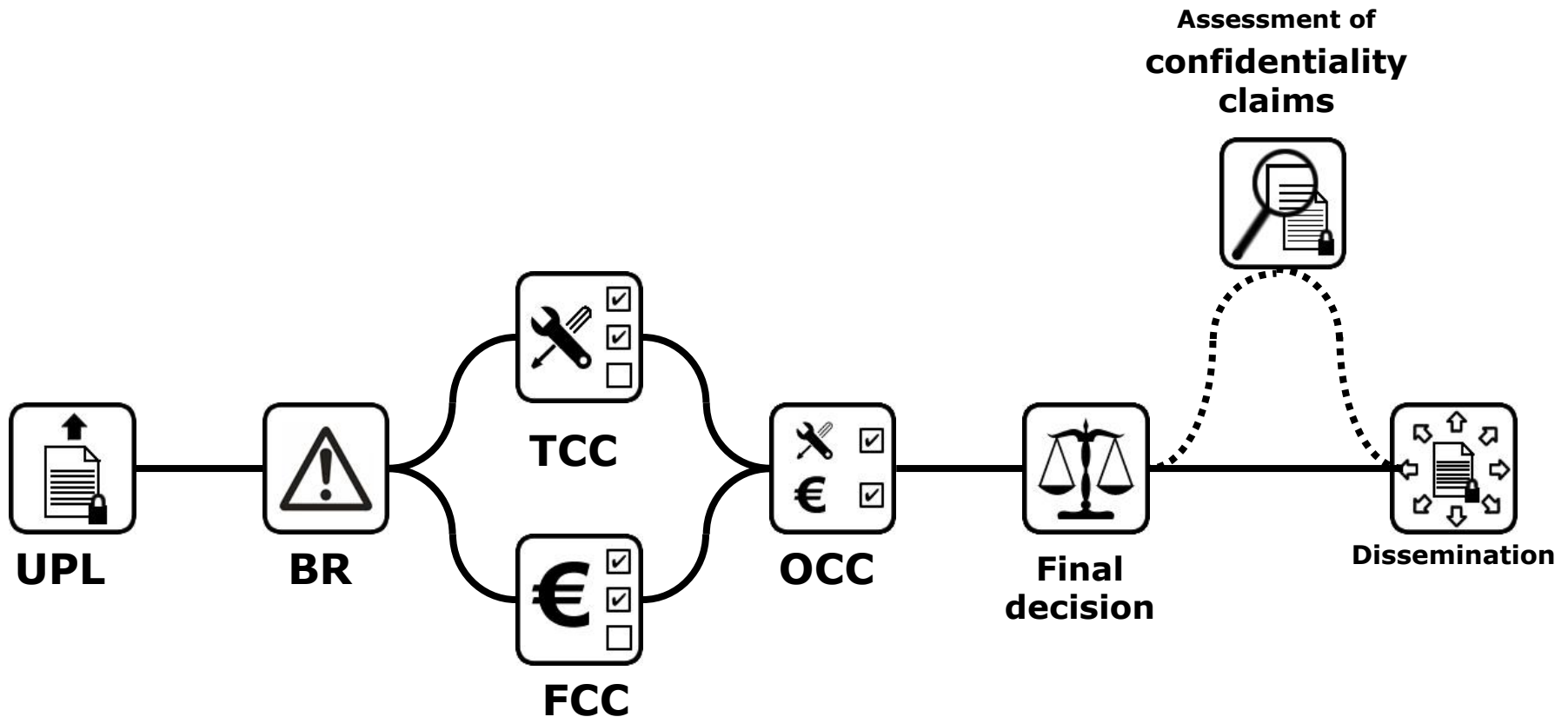
**Financial Completeness Check**

**Final decision**

**Confidentiality requests**



# Submission Pipeline in ECHA



# Technical Completeness Check



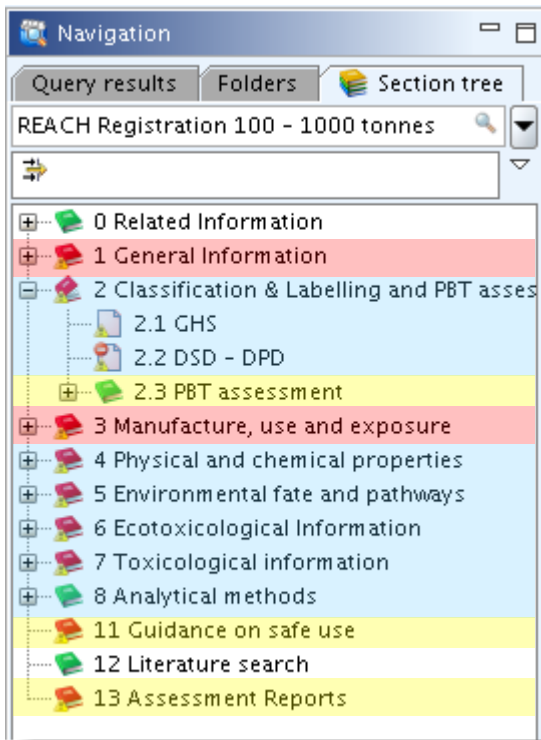
## Technical Completeness Check (TCC)

- ECHA carries out according to Article 20(2) of REACH
- Completeness:
  - Technical Completeness Check (TCC)
  - Financial Completeness Check (FCC)
- Verification of presence of information
  - Not an assessment at this step
- Completeness ≠ Compliance

## Information Requirements

- All registration dossiers regardless of tonnage band: Annex VI - Identity of registrant, Substance ID, C&L, Uses, etc.
- All registration dossiers with non-intermediate tonnage above 10 tonnes a year: Chemical safety report
- Depending on tonnage band: Annex VII – Annex X (cumulatively)

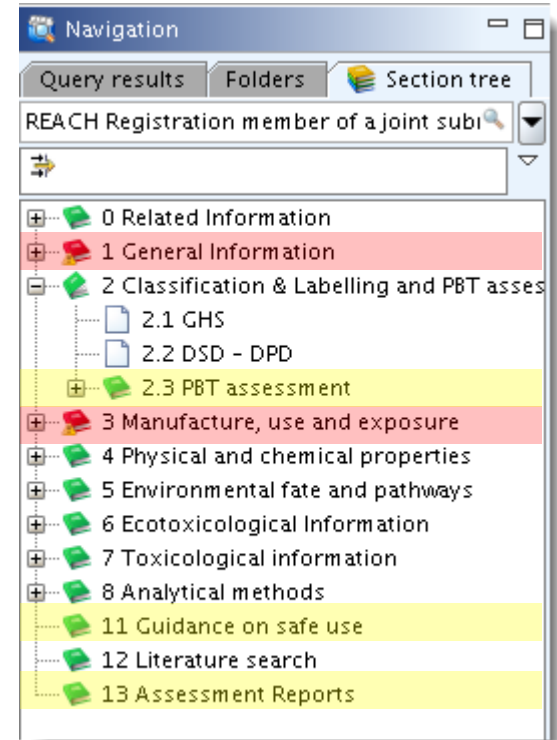
# Substance dataset – Joint Submission



- Information submitted by each registrant in their own dossier.

- Information submitted only by the LEAD registrant on behalf of the JS (unless member registrant opts out).

- Information submitted by the LEAD on behalf of the JS, or individually by each registrant, according to agreement.



# The Process of Technical Completeness Check

- Dossier MUST pass business rules first
- ECHA will perform the TCC on the dossier
  - Within 21 days for dossiers submitted by the end of March
  - Within 3 months if submitted April – May 2013 (only for deadline relevant registrations)
- Result communicated to registrant via REACH-IT



## TCC Update Request letter

- Sent to the registrant via REACH-IT, includes:
  - Deadline for resubmission (120 days for registration dossiers)
  - List of missing information
  - Instructions on how to proceed
  - Links to relevant support pages (manuals, guidance, etc.)
- Registrant has only one possibility to update the dossier

## TCC Resubmission

- Has to be done within the deadline given in the letter
  - If that deadline is missed, dossier is rejected
- Important in the IUCLID dossier
  - Dossier is a requested update
  - Correct last submission number
  - Correct communication number
- All the necessary information to succeed is in the update request letter

# AVOID mistakes – use the TCC plug-in!

The screenshot shows a file explorer window on the left with a context menu open. The 'Run TCC...' option is highlighted. The main window is titled 'Technical completeness check' and contains a table of results. The table has columns for 'Section number', 'Section name', 'Document name', 'Failure description', and 'Type'. The first row shows a 'TCC failure' for 'Section 1.3 Assessment Reports'. The second row shows a 'BR failure' for 'Section 2.3 PBT assessment'. The third row shows another 'BR failure' for 'Section 2.3 PBT assessment'. The interface also includes a filter dropdown set to 'Show all' and 'with type failure, warning', and version information for the TCC engine (7.00), Business rules (2.2.10), and Completeness rules (2.2.8).

Section number	Section name	Document name	Failure description	Type
Section 1.3	Assessment Reports		Section 1.3 is invalid or missing. A CSR or a justification for not providing a CSR must be included. - In order to submit a CSR, one must select 'REACH Chemical safety report (CSR)' in the field 'Type of report' and attach the CSR in the field 'Document'. - In order to submit a justification for not providing a CSR, one must select 'REACH Chemical safety report (CSR)' in the field 'Type of report' and provide the justification for not providing the CSR either in the field 'Remarks' or in the field 'Discussion'. - If you are providing another type of assessment report in addition to a CSR, you must make a selection in 'Type of report' and attach the report in the field 'Document', or include text in the field 'Remarks' or in the field 'Discussion'.	TCC failure
Section 2.3	PBT assessment		Failure in Business Rule BR164	BR failure
Section 2.3	PBT assessment		Section 2.3 of your dossier is incomplete. An endpoint summary must be created, and a selection must be made in the picklist under 'PBT assessment: overall result'. If the option 'PBT assessment does not apply' is selected, the field 'Justification' must also be provided.	BR failure

Further information: Webinar of 22 November 2012

<http://echa.europa.eu/web/guest/support/training-material/webinars>

# Financial Completeness Check



## Financial Completeness Check (FCC)

- Invoice (if applicable) is issued parallel to TCC
- Strict deadlines
  - 14 days initial due date (30 days when submission in April – May 2013)
  - 60 days extended due date – Reminder sent automatically
- Only electronic invoice => REACH-IT

## Invoice Sent by ECHA includes:

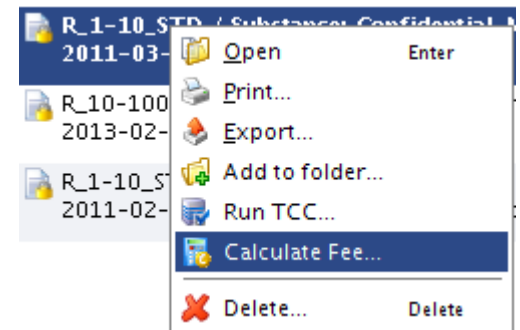
- Information about the submitting company and the submission itself
  - Invoice cannot be modified – keep your company data up to date in REACH-IT
- Chargeable items
  - Registration fee
  - Confidentiality claims
- ECHA's bank details

## **Registration Fee is determined by**

- Type of registration
- Tonnage band
- Company size
- Initial or update submission
- Individual or joint submission
- Potential chargeable confidentiality claims

## Fee Calculation Plug-in

- Available for free from IUCLID website
  - <http://iuclid.echa.europa.eu>
- Simulates the invoicing process
- Final fee to be paid is determined by invoice issued by ECHA
- Can only be run on dossiers





## Before Submission

- Verify your company specific information
  - Billing organisation name
  - Billing address
  - VAT number
- Company size (SME status)
  - Lower fees for SMEs

## Correct Company Size

- SME defined according to EC Recommendation 2003/361/EC
  - Online SME test:  
[http://ec.europa.eu/research/sme-techweb/index\\_en.cfm](http://ec.europa.eu/research/sme-techweb/index_en.cfm)
- Discount for SMEs
  - Information has to be valid at the time of submission
  - In case of mistake, notify ECHA
  - Formal SME verification by ECHA

## Challenges Related to FCC

- Incorrect company information => invoicing department refuses to pay
  - **AVOID mistakes – verify company information in REACH-IT!**
- Unexpected invoice e.g for confidentiality requests
  - **AVOID mistakes - use the Fee calculation plug-in!**

Further information: Webinar of 22 November 2012  
<http://echa.europa.eu/web/guest/support/training-material/webinars>

# Final decision



## Decision Letter

- Dossiers accepted for processing receive decision letter
  - Overall Completeness check = TCC + FCC
  - Depending on OCC outcome, either a positive or a negative decision is sent the registrant
  - **LEAD has to be successful before any member can get their registration number!**
- Positive decision
  - Registration number assigned
  - Information stored in ECHA's database
- Negative decision
  - Fees paid are not reimbursed
  - Registrant can submit a new initial dossier and start the process again

# Monitor progress of your submission in REACH-IT submission report

The list below displays the internal messages that were sent to you the last 30 days. To view all internal messages, click on the **Message box folder**  | [User folder](#) | [Organisation folder](#) | [Role folder](#) | [Deleted messages](#)

[Select All](#) | [Select None](#)

Select	Details	Read	Subject	Creation Date
<input type="checkbox"/>	<a href="#">▶ Show</a>	Yes	Dossier reached end of the pipeline (LN143899-08)	18/01/2013 22:25
<input type="checkbox"/>	<a href="#">▶ Show</a>	No	Reference number assigned (LN143899-08)	18/01/2013 22:22
<input type="checkbox"/>	<a href="#">▶ Show</a>	No	Completeness Check Outcome (LN143899-08)	18/01/2013 22:22
<input type="checkbox"/>	<a href="#">▶ Show</a>	No	Invoice has been opened - LN143899-08	18/01/2013 22:21
<input type="checkbox"/>	<a href="#">▶ Show</a>	Yes	Business Rules Check passed	18/01/2013 22:20
<input type="checkbox"/>	<a href="#">▶ Show</a>	Yes	File under examination (LN143899-08) - Registration (reg.)	18/01/2013 22:20

[Delete](#) | [Move to...](#) | [Message box folder](#) ▼

No.	Task	Remark	Result
1.	Virus check	-	Succeeded
2.	File format validation	-	Succeeded
3.	Check XML structure	-	Succeeded
4.	Enforce Rules	-	Succeeded
5.	Store Dossier	-	Succeeded
6.	Create Substance Identity	-	Succeeded
7.	Assign MSCAs	-	Succeeded
8.	Technical Completeness Check	-	Succeeded
9.	Pay Submission Fee	-	Succeeded
10.	Overall Completeness Check	-	Succeeded
11.	Issue Reference Number	-	Succeeded
12.	End of Pipeline Activities	-	Succeeded
13.	Data Dissemination	-	Skipped
14.	Trigger WorkFlow	-	Succeeded

# Confidentiality requests



## Claiming Information Confidential

- Information listed in 119(1) of REACH is always published
  - Use the [IUCLID Dissemination plug-in](#)
- Information listed in 119(2) of REACH can be claimed confidential
  - Fee on confidentiality claim to be paid
  - Adequate justification must be provided
- Fee depends on claim type, company size and joint submission status
  - Use the [IUCLID Fee Calculation plug-in](#)



## Further information about dissemination and confidentiality claims:

Data Submission Manuals at

<http://echa.europa.eu/web/guest/support/dossier-submission-tools/reach-it/data-submission-industry-user-manuals>

- DSM 15 + technical annexes about dissemination
- DSM 16 about making confidentiality requests
- DSM 17 if IUPAC name claimed confidential, public name has to be provided

Q&A on dissemination and confidentiality claims of Safety Data Sheet information in IUCLID 5.4 at

<http://echa.europa.eu/web/guest/support/faqs>

## Key Messages

- After the submission, monitor your REACH-IT account to receive all the communications from ECHA
- Pay the invoice within the given deadline



**Thank you!**

