

Important steps after dossier submission

How to Prepare and Submit a
Member Dossier

5th March 2013

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ECHA



Agenda

- Business Rules Verification
- Technical Completeness Check
- Financial Completeness Check
- Final Decision
- Confidentiality Request

Business Rules Verification (BR)

- Administrative check
- Checked in REACH-IT
 - Format: verification of information
 - Administrative: certain information must be present in the dossier to be able to handle it
- If passed, dossier is accepted for processing

What happens in REACH-IT

- Details
- Submission Report
- Status of processes
- Content
- Accounting
- Annotations
- Comments

Passed Tasks			
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	-	Started
9.	Pay Submission Fee	-	Started
10.	Overall Completeness Check	-	Not Performed Yet
11.	Issue Reference Number	-	Not Performed Yet
12.	End of Pipeline Activities	-	Not Performed Yet
13.	Data Dissemination	-	Not Performed Yet
14.	Trigger WorkFlow	-	Not Performed Yet

Labeling

Message box View my messages

Downstream user

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

Select All | Select None

Select	Details	Read	Subject	Creation Date
<input type="checkbox"/>	Show	Yes	Business Rules Check passed	10/01/2013 22:20
<input type="checkbox"/>	Show	Yes	File under examination (LN143899-08) - Registration (reg.)	10/01/2013 22:20

Most common Business Rule failures in initial dossiers

Business Rule	Short description of the rule
1 BR131	The legal entity indicated in the dossier header and/or in section 1.1 Substance identification of your IUCLID 5 dossier is different from the one used to submit the dossier in REACH-IT.
2 BR027	In case the JS name indicated in REACH IT is not for the correct substance ID , error message is 'The substance identity in your dossier does not correspond to the information available in the joint submission you have indicated in REACH IT during the submission of this dossier.' In case no JS was indicated in REACH IT but the company is part of a JS for the same substance , the error message is 'The system has detected that you are part of a Joint Submission for this substance. You have to indicate the Joint Submission name during the submission in REACH IT'.
3 BR024	The IUCLID 5 template used in your dossier is not valid for this submission type.

- Manual: Data Submission Manual 4 – How to Pass Business Rule Verification

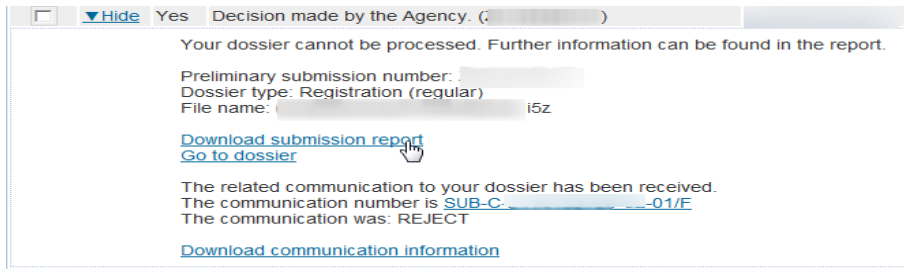
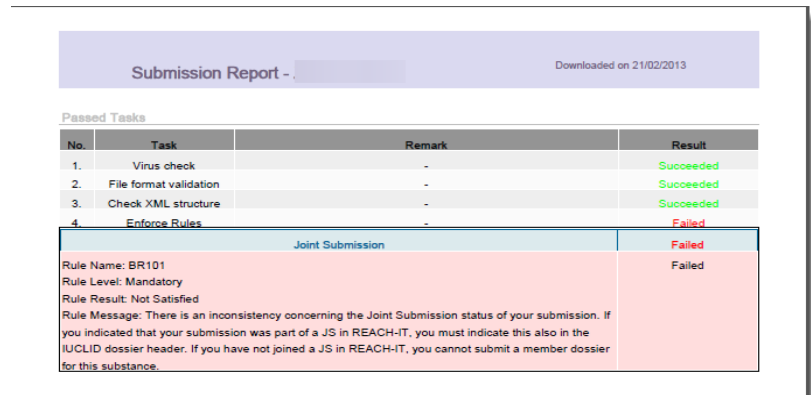
<http://echa.europa.eu/web/guest/support/dossier-submission-tools/reach-it/data-submission-industry-user-manuals>

- Webinar: Registration process I: Business Rules – What they are and how to pass them

http://echa.europa.eu/web/guest/view-article/-/journal_content/ac5c7739-a57d-41a3-9163-be762eafeab0

What If You Have Failed Business Rules?

- Communication is sent to REACH-IT mailbox
 - Check submission report

Submission Report - [redacted] Downloaded on 21/02/2013

Passed Tasks


No.	Task	Remark	Result
1.	Virus check	-	Succeeded
2.	File format validation	-	Succeeded
3.	Check XML structure	-	Succeeded
4.	Enforce Rules	-	Failed

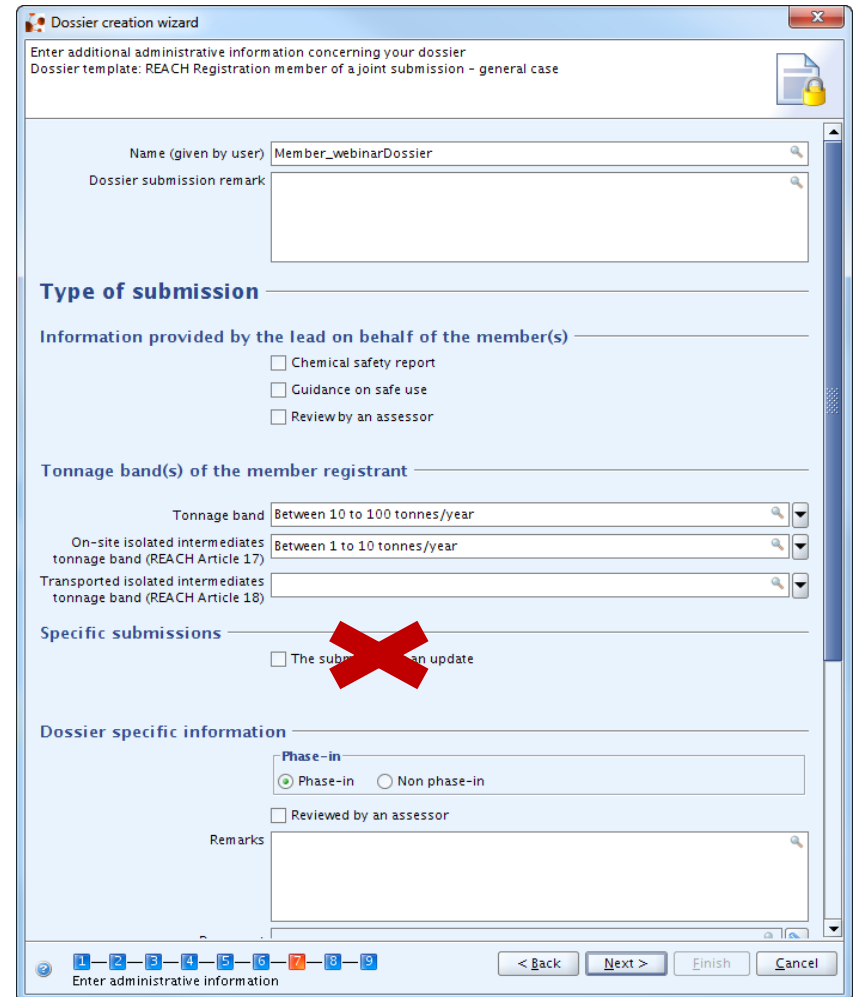
Joint Submission

Rule Name: BR101	Failed
Rule Level: Mandatory	Failed
Rule Result: Not Satisfied	Failed
Rule Message: There is an inconsistency concerning the Joint Submission status of your submission. If you indicated that your submission was part of a JS in REACH-IT, you must indicate this also in the IUCLID dossier header. If you have not joined a JS in REACH-IT, you cannot submit a member dossier for this substance.	Failed

- Don't panic!
 - You can resubmit as many times, as needed
 - No fee is charged related to these BR failures
 - No deadline for resubmission (except REACH deadline 31th of May 2013 still applies for 100-1000t/year dossiers)

If your **initial** dossier fails in Business Rules then...

- Identify the failure. Correct it. Dossier can not be modified, editing is only allowed in 'substance dataset' mode. 
- Create the new dossier. Do not tick 'The submission is an update' box.
- Check your new dossier with the TCC tool!



Technical Completeness Check (TCC)



Technical Completeness Check (TCC)

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

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 from the registration deadline if submitted April – May 2013 (only for deadline relevant registrations)
- Result communicated to registrant via REACH-IT

The 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

Financial Completeness Check



Financial Completeness Check (FCC)

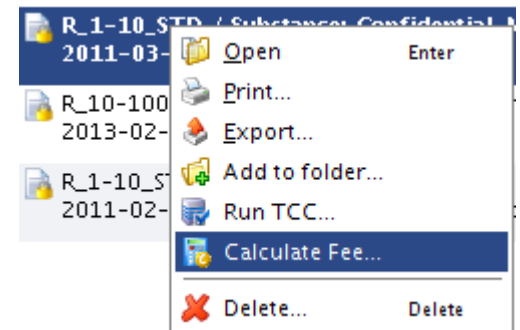
- Invoice (if applicable) is issued parallel to TCC
- Strict deadlines
 - 14 days initial due date (30 days when submission in April – May 2013)
 - 60 days extended due date – Reminder sent automatically
- Only electronic invoice => REACH-IT
- Chargeable items
 - Registration fee
 - Confidentiality claims

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
- Discount for SMEs
 - Information has to be valid at the time of submission
 - In case of mistake, notify ECHA
 - Formal SME verification by ECHA


Final Decision



Decision Letter

- Dossiers accepted for processing receive a decision letter
 - Overall Completeness check = TCC + FCC
 - Depending on OCC outcome, either a positive or a negative decision is sent to the registrant
 - **MEMBER gets his registration number only after the lead is successful!**
- Positive decision
 - Registration number assigned
 - Information stored in ECHA's database

Monitor the progress of your submission in REACH-IT

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

Select All | Select None

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

[Hide](#) Yes Decision made by the Agency. ()

Your dossier cannot be processed. Further information can be found in the report.

Preliminary submission number: [redacted]
 Dossier type: Registration (regular)
 File name: [redacted] i5z

[Download submission report](#)
[Go to dossier](#)

The related communication to your dossier has been received.
 The communication number is SUB-C-[redacted]-01/F
 The communication was: REJECT

[Download communication information](#)

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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 the 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

- Use the provided supporting tools (plug-ins, webinars, manuals, etc.)
- Monitor your REACH-IT account
- Business Rules step must pass BEFORE the deadline
- Pay the invoice within the given deadline

Thank you!

