

Making Your Registration Successful

Common Business Rule Mistakes

08. 09. 2010

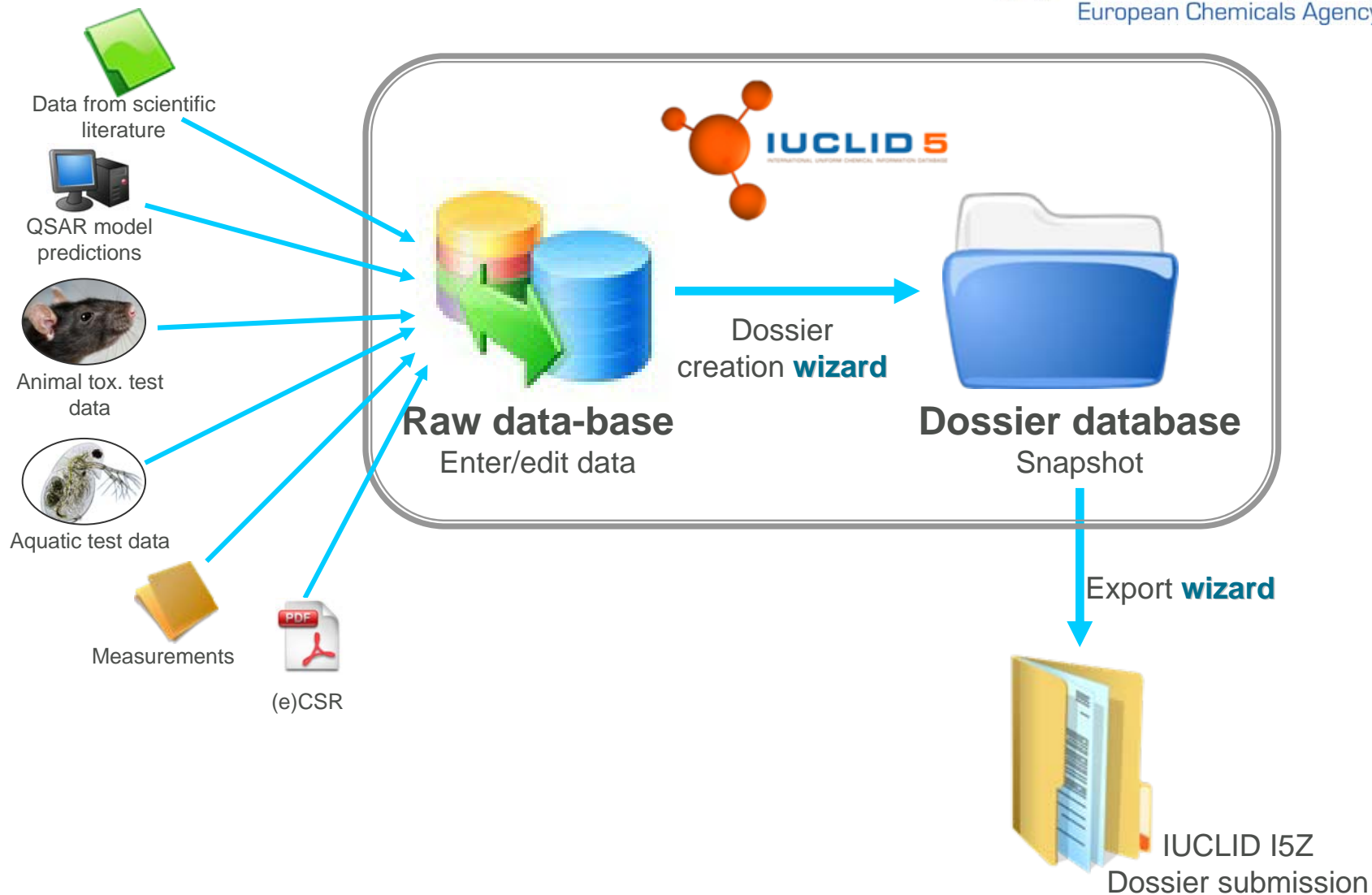
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ECHA – Registration and Dossier Submission Unit

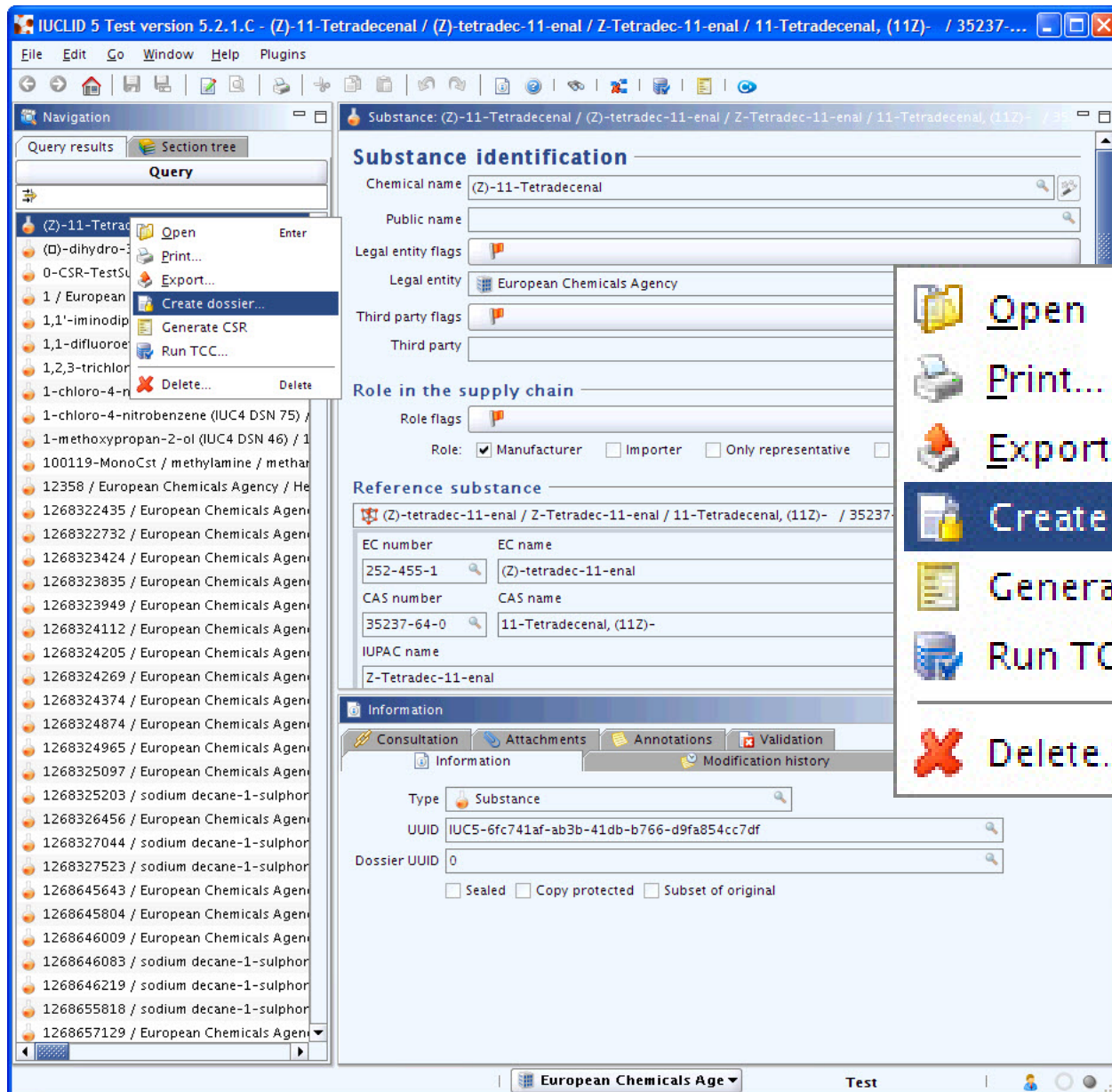
Agenda

- Short overview of dossier creation
- Registration process
- What are business rules
 - Mandatory business rules
 - Overrutable business rules
- Most common reasons for failing business rule verification
- Most common Helpdesk cases
- Further support

IUCLID 5 - fundamentals



Dossier creation



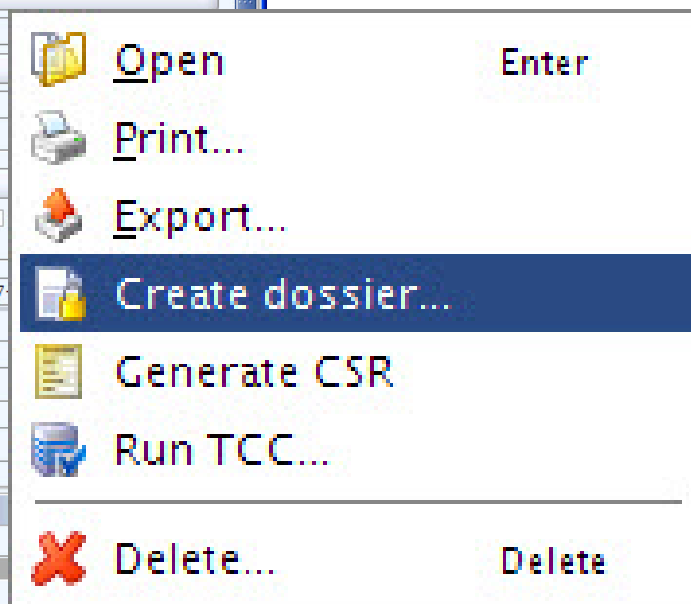
The screenshot shows the IUCLID 5 Test version 5.2.1.C interface. The main window displays the 'Substance identification' and 'Reference substance' sections. A context menu is open over the 'Reference substance' table, listing actions: Open, Print..., Export..., Create dossier..., Generate CSR, Run TCC..., and Delete... The 'Create dossier...' option is highlighted in blue. The 'Reference substance' table contains the following data:








EC number	EC name
252-455-1	(Z)-tetradec-11-enal
CAS number	CAS name
35237-64-0	11-Tetradecenal, (11Z)-
IUPAC name	Z-Tetradec-11-enal

The 'Information' section shows the following details:

- Type: Substance
- UUID: IUCS-6fc741af-ab3b-41db-b766-d9fa854cc7df
- Dossier UUID: 0
- Sealed:
- Copy protected:
- Subset of original:

Raw data-base
Enter/edit data



-  **Open** Enter
-  **Print...**
-  **Export...**
-  **Create dossier...**
-  **Generate CSR**
-  **Run TCC...**
-  **Delete...** Delete

Dossier creation wizard

Dossier creation wizard

Select a dossier template which meets your specific requirements:
regulatory programme, type of dossier, tonnage band, member of a joint submission, etc.

Substance

Dossier templates available for a substance:

- Complete
- Biocides - Active ingredients
- Biocides - Biocidal products
- Biocides - Substances of concern
- CLP notification
- CLP Regulation - CLH dossier
- Endpoints information
- OECD harmonised templates
- OECD SIDS
- REACH Annex XV - Restriction
- REACH Annex XV - SVHC
- REACH Application for authorisation
- REACH Downstream user report
- REACH Inquiry
- REACH Notification of substance in article
- REACH PPORD
- REACH Registration 1 - 10 tonnes, physicochemical requirements**
- REACH Registration 1 - 10 tonnes, standard requirements
- REACH Registration 10 - 100 tonnes
- REACH Registration 100 - 1000 tonnes
- REACH Registration above 1000 tonnes
- REACH Registration member of a joint submission - general case
- REACH Registration member of a joint submission - intermediates
- REACH Registration on-site isolated intermediates above 1 tonne
- REACH Registration transported isolated intermediates 1 - 1000 tonnes
- REACH Registration transported isolated intermediates above 1000 tonnes
- REACH Substance Evaluation

Note: The dossier template is used to determine which substance endpoints will be selected by default. The selection can be modified manually in a subsequent step of the dossier creation

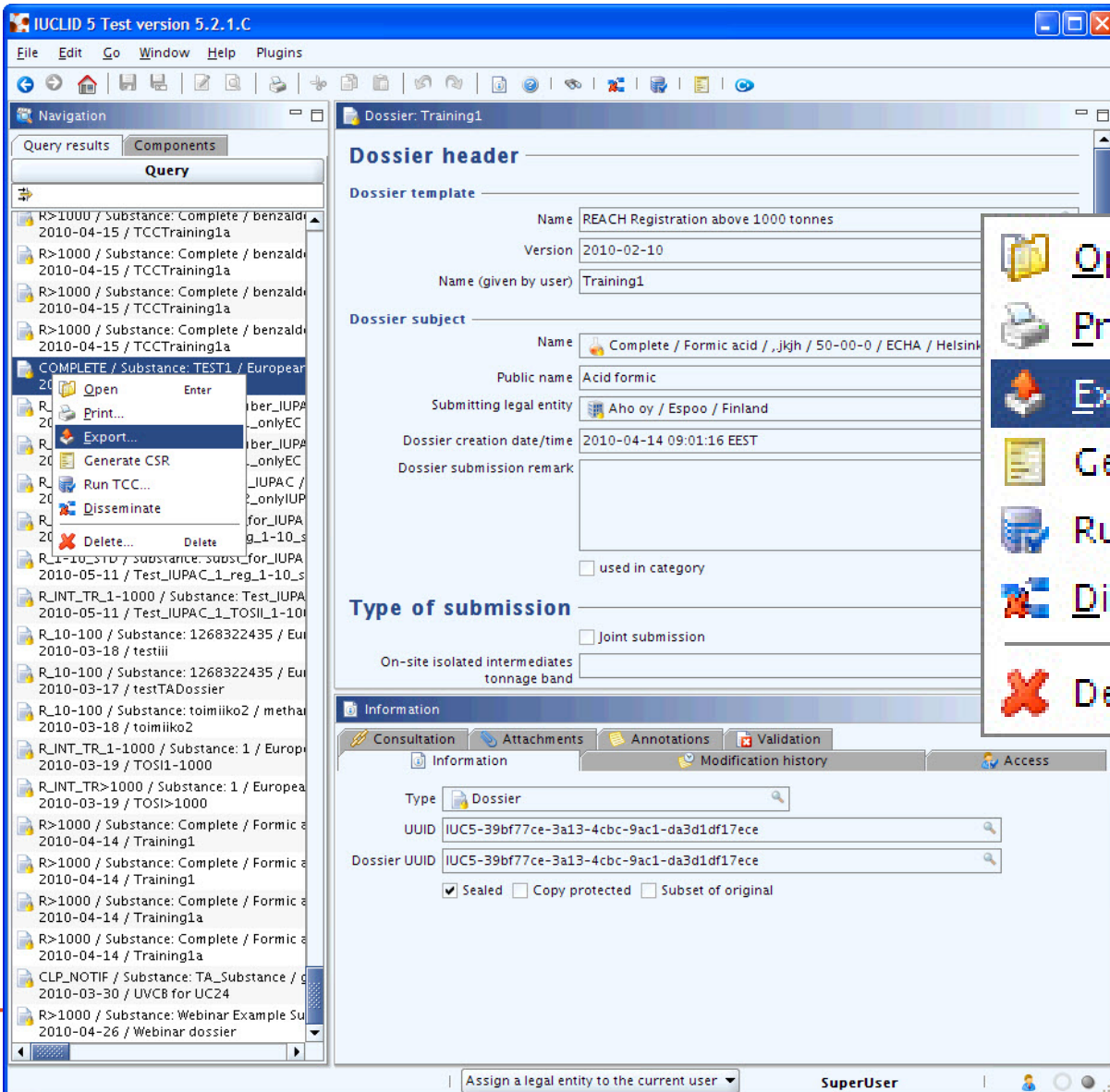
1 2 3 4 5 6 7 8

Select a dossier template

< Back Next > Finish Cancel

Dossier export

Dossier database Snapshot



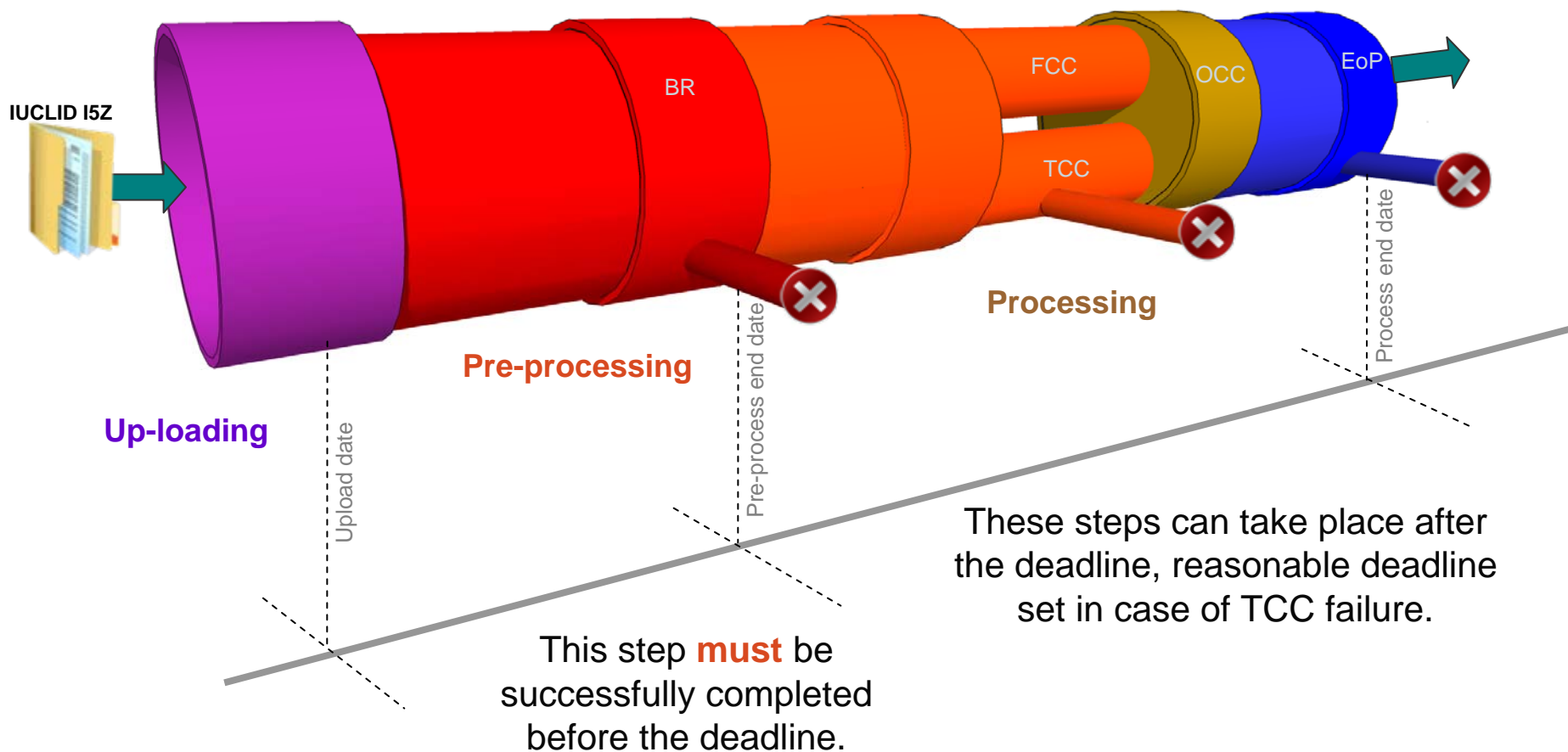
The screenshot shows the IUCLID 5 Test version 5.2.1.C interface. The main window displays a dossier titled "Dossier: Training1". The "Dossier header" section includes fields for Name (REACH Registration above 1000 tonnes), Version (2010-02-10), Name (given by user) (Training1), Dossier subject Name (Complete / Formic acid / ,,jkh / 50-00-0 / ECHA / Helsinki), Public name (Acid formic), Submitting legal entity (Aho oy / Espoo / Finland), Dossier creation date/time (2010-04-14 09:01:16 EEST), and Dossier submission remark. The "Type of submission" section has checkboxes for "used in category" and "Joint submission". The "Information" section shows fields for Type (Dossier), UUID (IUCS-39bf77ce-3a13-4cbc-9ac1-da3d1df17ece), and Dossier UUID (IUCS-39bf77ce-3a13-4cbc-9ac1-da3d1df17ece), with checkboxes for Sealed, Copy protected, and Subset of original.

A context menu is open over the dossier, listing the following actions:

- Open (Enter)
- Print...
- Export...
- Generate CSR
- Run TCC...
- Disseminate
- Delete... (Delete)

The bottom status bar shows "Assign a legal entity to the current user" and "SuperUser".

Submission pipeline



This step **must** be successfully completed before the deadline.

Earlier submission recommended!

These steps can take place after the deadline, reasonable deadline set in case of TCC failure.

Critical steps of the registration process

- **Business Rule verification**
 - Failure rate down from 40 to 25%
- **Technical Completeness Check**
 - Since the introduction of the TCC tool low failure rate (<5%)
- **Financial Completeness Check**
 - Important to pay the invoice in time (very rare reason for rejection, <1%)

What are business rules?

- Administrative check
- Checked in REACH-IT
 - Format: Correct format
 - Administrative: Certain information must be in the dossier to be able to handle it
- If passed, dossier is accepted for processing

Mandatory vs. Overrutable Business Rules

- **Mandatory business rules:**
 - Majority of BRs
 - Automatic check
- **Overrutable business rules:**
 - Already exist
 - Manual check
- Both have to be successfully passed to be accepted for processing

Top 10 Business Rule Failures* ECHA

European Chemicals Agency

	BR	What is the BR	% of all BR failures	TCC tool
1	BR131	Legal Entity	24.1%	Partially
2	BR090	Mono-constituent substance vs. 1.2	8.1%	Yes
3	BR020	EC/CAS/IUPAC must be present for all reference substance	7.6%	Yes
4	BR019	Minimum one constituent must be present in S1.2	4.9%	Yes
5	BR038	Spontaneous update (format check)	4.9%	Yes
6	BR091	Optional Joint Submission documents for members	4.7%	No
7	BR027	Incorrect Joint Submission Object name	3.8%	No
8	BR033	Initial vs. Update dossier	3.8%	No
9	BR082	Tonnage band comparison	3.8%	No
10	BR063	S1.5 must be empty if dossier is not part of a Joint Submission	2.8%	Yes
		All the other business rule failures	31.4%	

*during the first three weeks of August

<http://echa.europa.eu>

“Old” vs. “New” Top 10

- LE mismatch
- BR020
- BR024
- BR025
- BR033
- BR034
- BR038
- BR060
- BR082
- BR119
- BR131
- BR090
- BR020
- BR019
- BR038
- BR091
- BR027
- BR033
- BR082
- BR063

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