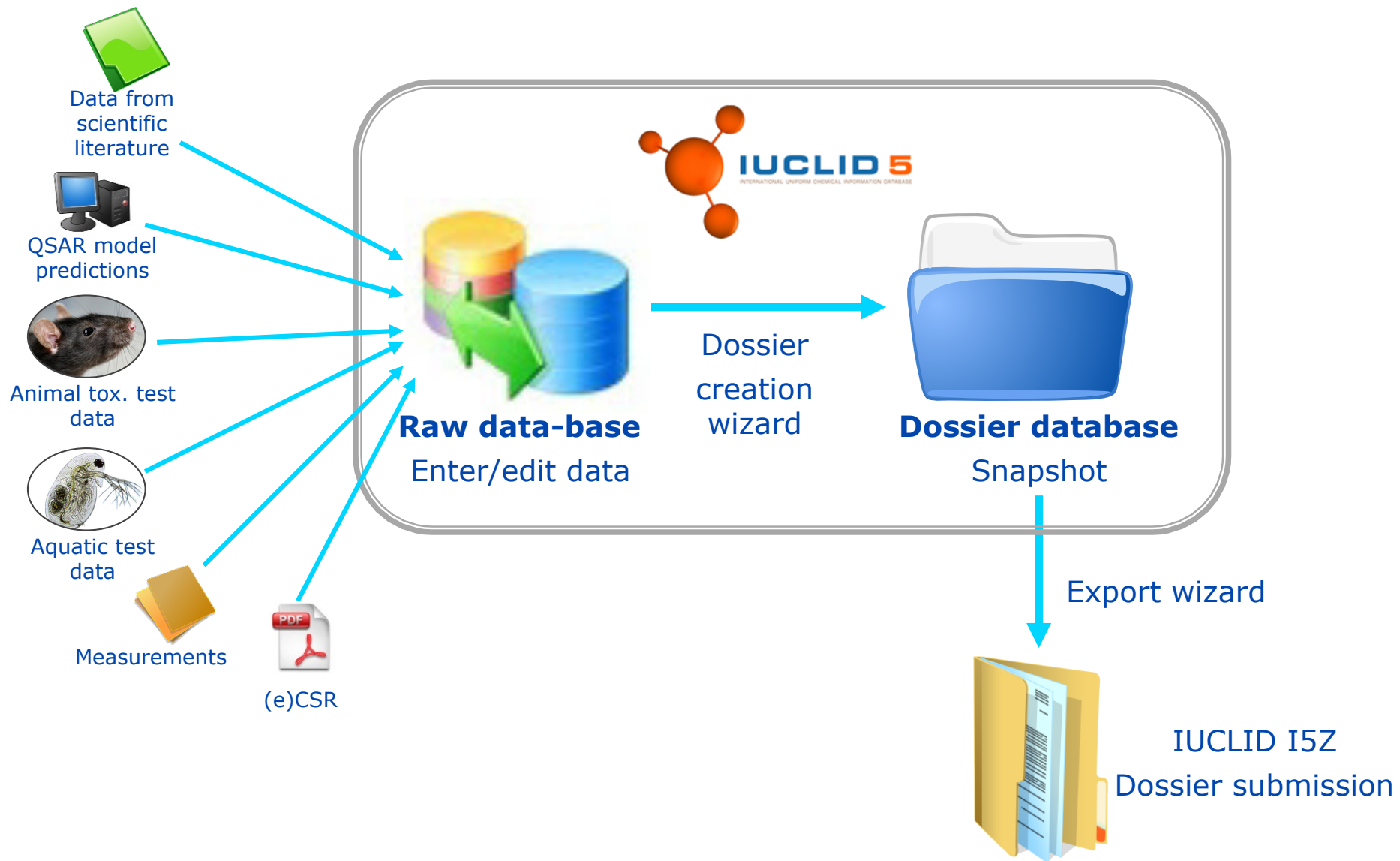


Short overview of dossier creation and the registration process

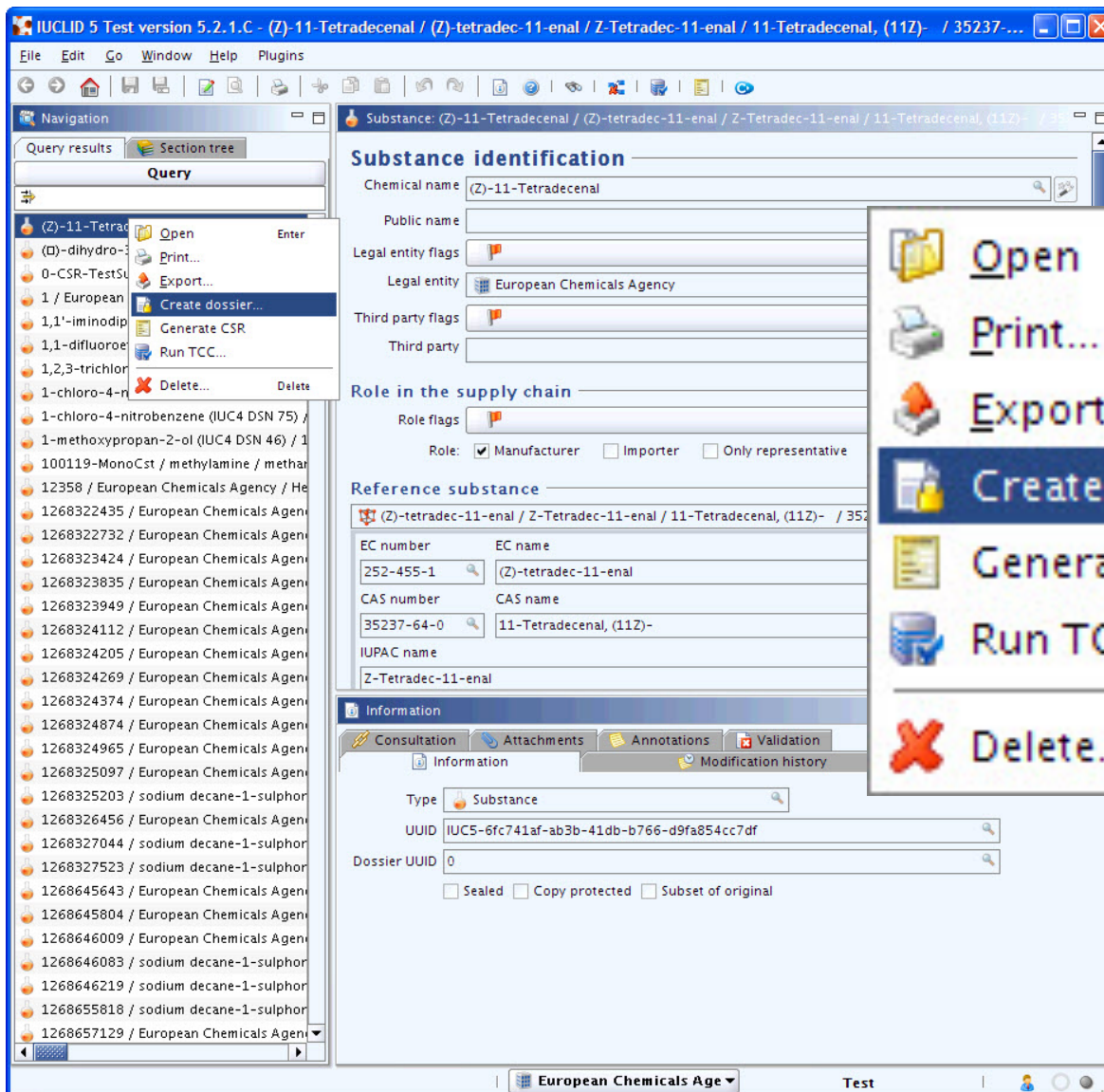


IUCLID 5 - fundamentals



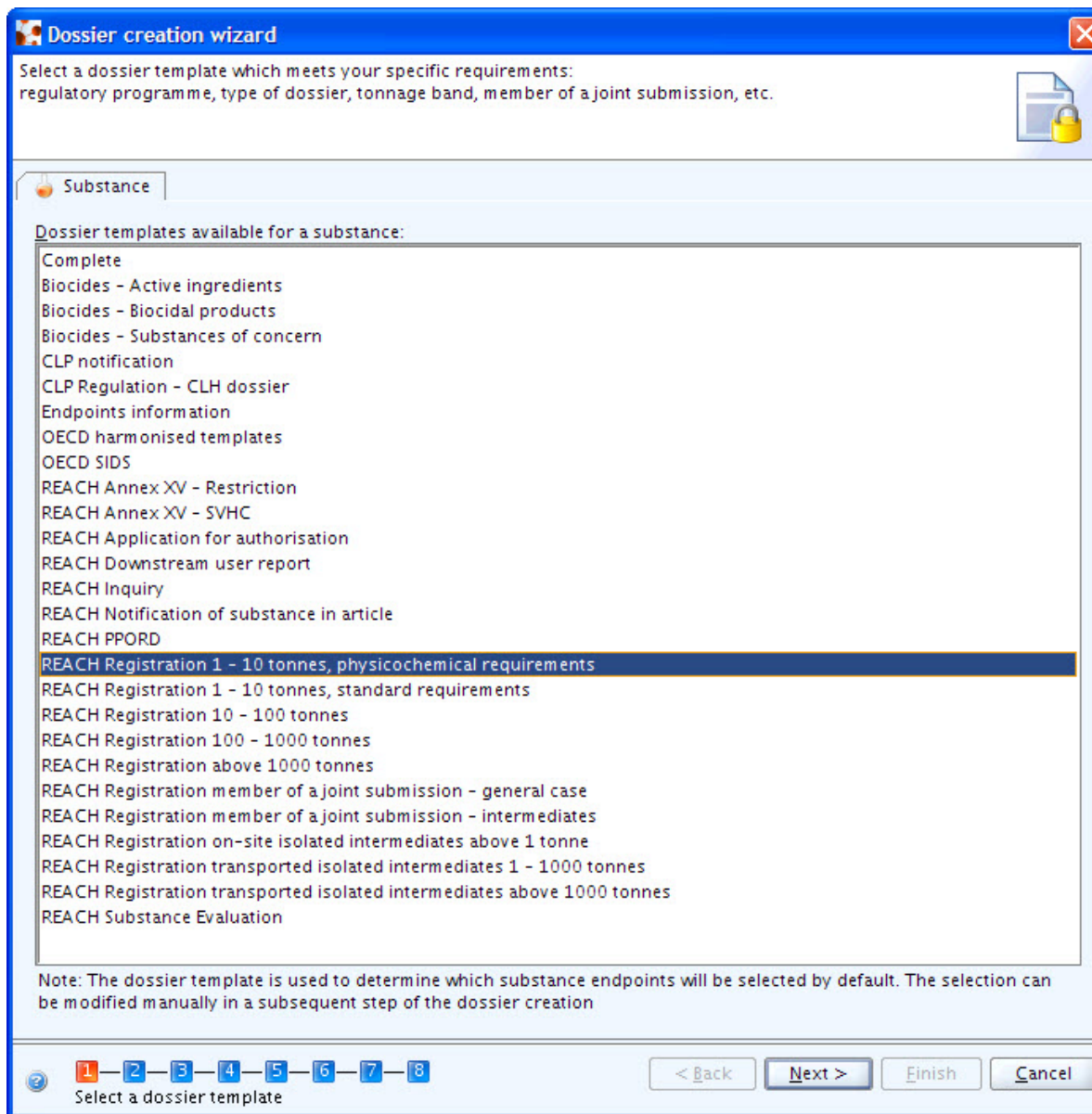
Dossier creation

Raw data-base
Enter/edit data



The screenshot shows the IUCLID 5 Test version 5.2.1.C interface. The left pane displays a list of substances, with a context menu open over the '(Z)-11-Tetradecenal' entry. The right pane shows the 'Substance identification' and 'Reference substance' details for '(Z)-11-Tetradecenal'. The 'Substance identification' section includes fields for Chemical name, Public name, Legal entity flags, Legal entity (European Chemicals Agency), Third party flags, and Third party. The 'Reference substance' section includes EC number (252-455-1), EC name ((Z)-tetradec-11-enal), CAS number (35237-64-0), CAS name (11-Tetradecenal, (11Z)-), and IUPAC name (Z-Tetradec-11-enal). The 'Information' section at the bottom shows the substance type, UUID (IUCS-6fc741af-ab3b-41db-b766-d9fa854cc7df), and Dossier UUID (0). A larger menu is overlaid on the right side of the screen, listing actions: Open (Enter), Print..., Export..., Create dossier..., Generate CSR, Run TCC..., and 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

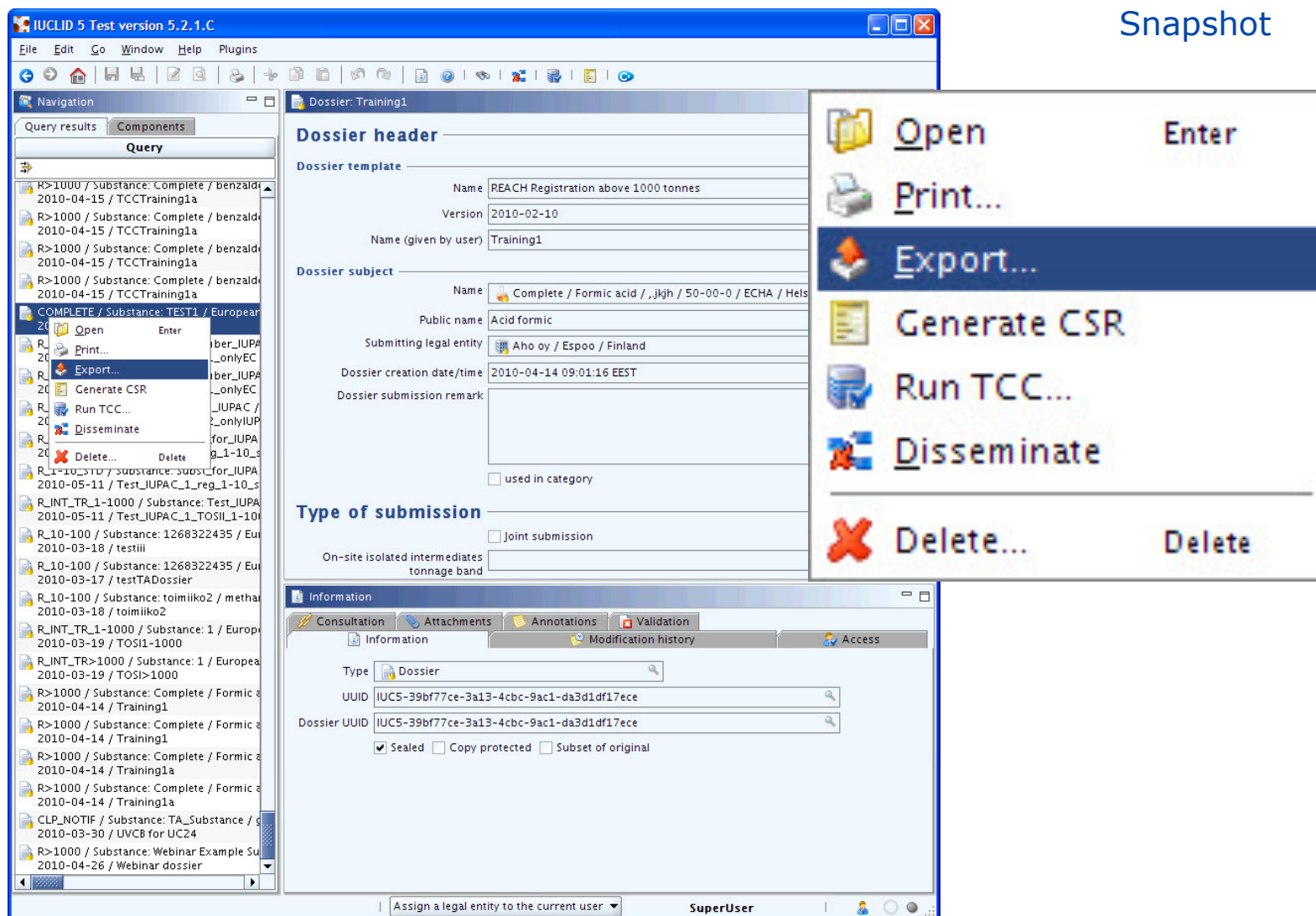
1 2 3 4 5 6 7 8

Select a dossier template

< Back Next > Finish Cancel

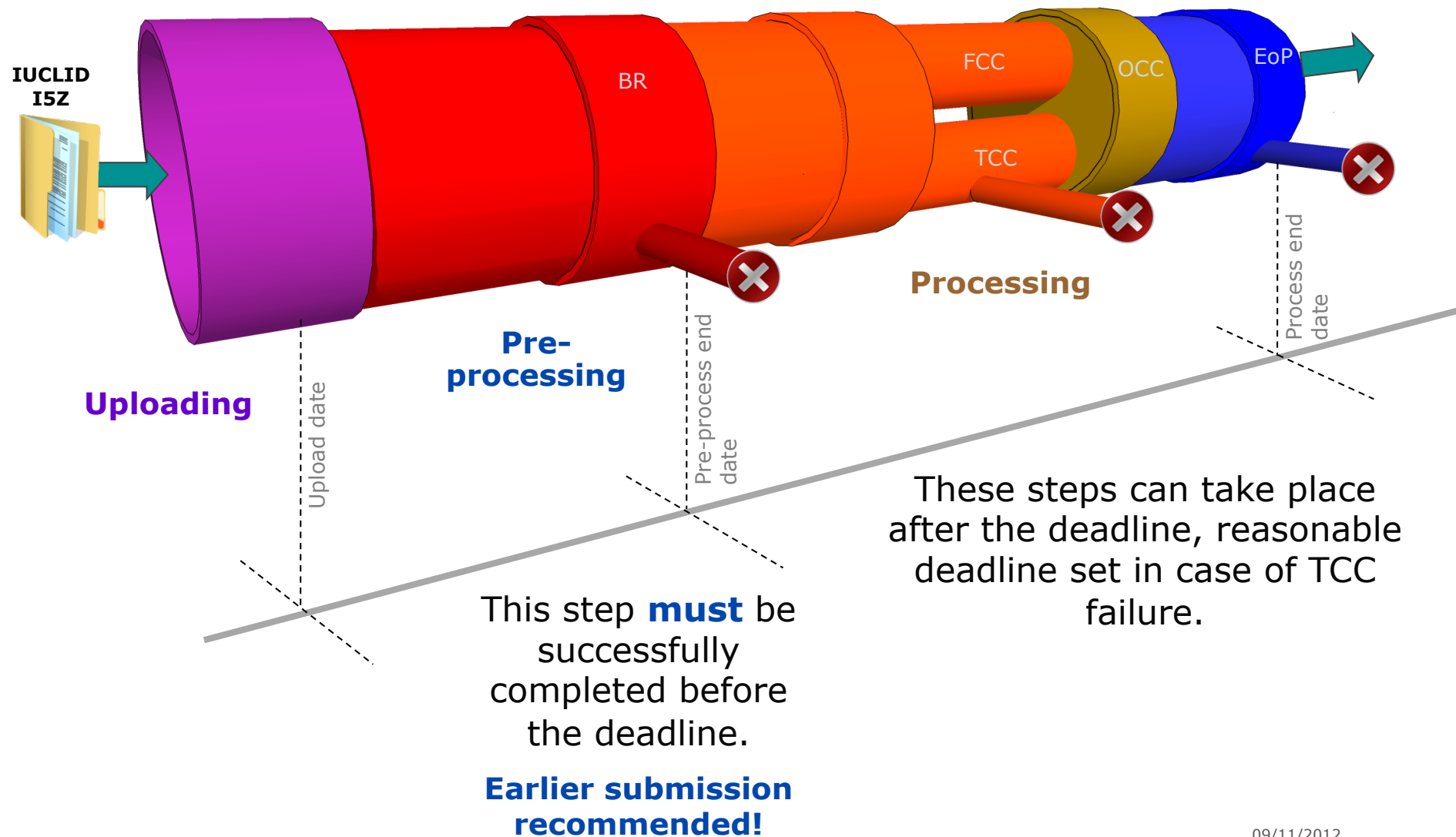
Dossier export

Dossier database Snapshot



The screenshot displays the IUCLID 5 Test version 5.2.1.C interface. On the left, a navigation pane shows a list of dossiers, with the 'Export...' option highlighted. On the right, the 'Dossier: Training1' header form is visible, containing fields for Name, Version, Name (given by user), Dossier subject, Public name, Submitting legal entity, Dossier creation date/time, and Dossier submission remark. Below the header form is the 'Type of submission' section with checkboxes for 'used in category' and 'Joint submission'. At the bottom, an 'Information' pane shows details for the selected dossier, including Type, UUID, Dossier UUID, and checkboxes for 'Sealed', 'Copy protected', and 'Subset of original'. A context menu is overlaid on the right side of the interface, listing actions: Open (Enter), Print..., Export..., Generate CSR, Run TCC..., Disseminate, and Delete... (Delete).

Submission pipeline



Critical steps of the registration process

- Business Rule verification
 - Failure rate increased since the registration deadline in 2010
- 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%)

Business rules

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 business rules
 - Automatic check
- Overrutable business rules:
 - Already exist
 - Manual check
- Both have to be successfully passed to be accepted for processing

Most Common Business Rules Failures

	BR	What is the BR	% of all BR failures
1	BR035	Incorrect last submission number	11%
2	BR131	Legal Entity	8%
3	BR082	Tonnage band comparison	6%
4	BR164	PBT assessment value	5%
5	BR027	Incorrect Joint Submission Object name	5%
6	BR091	Optional Joint Submission documents for members	5%
7	BR040	Incorrect reference number	4%
8	BR024	Equality of dossier type between IUCLID and REACH-IT	3%
9	BR020	Substance identification	3%
10	BR053	EC number from inquiry result	2%
		All the other business rule failures	48%

*during July 01 – October 17 2012

Thank You

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