How to improve the quality and consistency of the dossiers – and why

Eighth Stakeholders' Day

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Dossier quality and consistency

- **Background**
- ECHA’s activities
- Be proactive: what can you do?

Background – past five years

- REACH aims to advance knowledge on the properties and uses of substances:
  - Better safety and control measures;
  - Reduced risk for human health and the environment.
- REACH and CLP are working well:
  - Commitment and collaboration between ECHA, EU Member States, European Commission, industry and stakeholders;
  - Registration and Dissemination: wealth of information on properties and uses of chemicals collected and publically available;
- Eurostat Baseline study five years update reveals a ”marked increase in quality of data & better control of risk” as a result of first registration phase.

Review on REACH: http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=COM:2013:0049:FIN:EN:PDF
REACH Baseline update: http://epp.eurostat.ec.europa.eu/cache/ITY_OFFPUB/KS-RA-12-024/EN/KS-RA-12-024-EN.PDF

Quality concerns?

- Article 54 report: "…shows that a large part of the examined registration dossiers still raise quality and subsequently compliance concerns."
- Article 117.3 report: "Results from dossier evaluation conducted as part of compliance checks show that the use of read-across and category prediction methods are often not well-justified. In addition, the experimental data provided in the dossiers are in some cases also not sufficient to meet information requirements under REACH."

Article 54 report: http://echa.europa.eu/documents/10162/13628/evaluation_report_2012_en.pdf
Article 117.3 report: http://echa.europa.eu/documents/10162/13639/alternatives_test_animals_2011_en.pdf

Quality is important!

Information gathered through registration is main source for:

- **Industry:** Assess potential risks of chemicals and recommend safety advice at the work place and throughout the supply chain;
- **Authorities:** Verify that risks are adequately controlled or if needed, propose EU-wide regulatory risk management;
- **Public:** Get adequate information and make informed decisions as to the acceptability of using certain chemicals.

ECHA's Strategic Aims

ECHA'S STRATEGIC AIMS

- Maximise the availability of high quality data to enable the safe manufacture and use of chemicals.
- Mobilise authorities to use data intelligently to identify and address chemicals of concern.
- Address the scientific challenges by serving as a hub for scientific and regulatory capacity building of Member States, European institutions and other actors.
- Embrace current and new legislative tasks efficiently and effectively, while adapting to upcoming resource constraints.

Dossier quality and consistency

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- **ECHA's activities**
- Be proactive: what can you do?

ECHA's activities

- Registration:
  - Business rules, completeness check;
  - Article 36 requests for information, screening letters;
- Evaluation – dossier compliance checks:
  - General concern, full compliance, targeted compliance, areas of concern (AoC);
    - At least 5% will be formally evaluated;
    - For AoC the entire database can be the starting point;
- Dissemination:
  - (almost) all data is already published;
  - Improvements of dissemination website will make quality of information more transparent.

ECHA's activities – high numbers, high efficiency, high effectiveness

- ECHA focuses on the development of efficient and effective methods to analyse the information received to support dossier quality improvement activities.

Examples:

- Evaluation area of concern: activity to filter all dossiers with a specific issue and send a draft decision to registrants involved. In 2012, 295 compliance checks were carried out this way. More to be expected.

- Screening: based on analysis of all pure intermediate dossiers, 2 388 letters were sent informing registrants about potential non-compliances. Over 80% of the dossiers were updated. The remaining 20% are under scrutiny.

Substance identity quality improvement roadmap

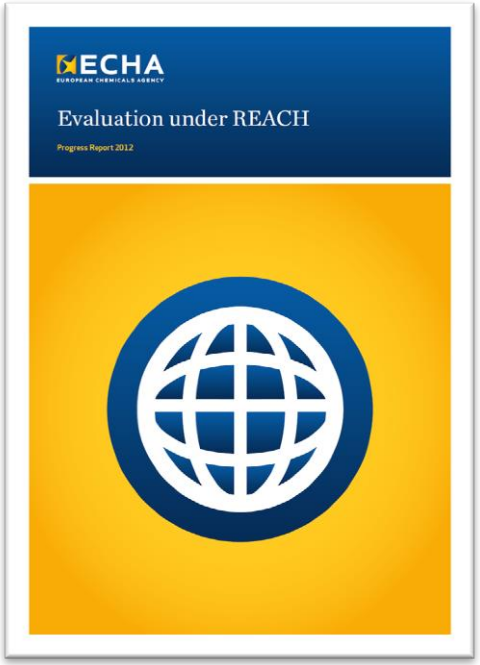
- Approach:
  - Use of computational screening to more efficiently identify dossiers with potential Substance IDentity (SID) concerns;
- Planned activities:
  - Screening of dossiers already submitted for 2013 deadline:
    - support to registrants in improving SID information;
  - Identification of dossiers with severe SID deficiencies;
  - Mass screening of all dossiers with selected algorithms.
- Spontaneous updates expected as a response;
- Art. 36 letters or compliance check as tools to address non-responsive registrants.

Dossier quality and consistency

- Background
- ECHA's activities
- **Be proactive: what can you do?**

Be proactive…

- Read the Evaluation reports reflecting the dossier quality findings:
  - Progress of activities;
  - Information on common pitfalls.
- Recommendations for registrants:
  - Identify your substance clearly;
  - Make sure test material is representative;
  - Make full use of all relevant information;
  - Provide clear use and exposure information;
  - Make use of ECHA support.
- View the webinars with tips on how to improve dossier compliance.

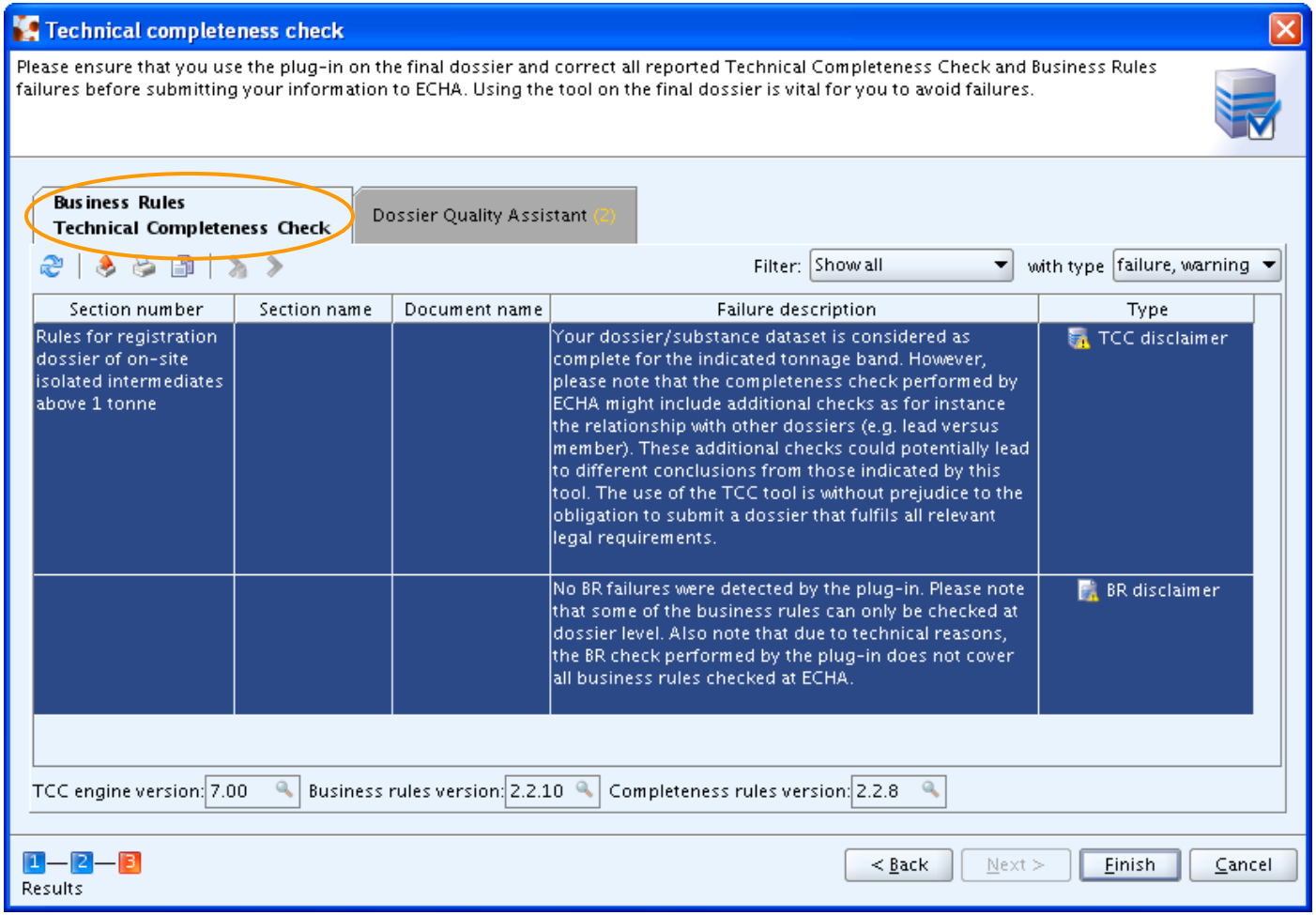


EHCA webinars: http://echa.europa.eu/support/training-material/webinars

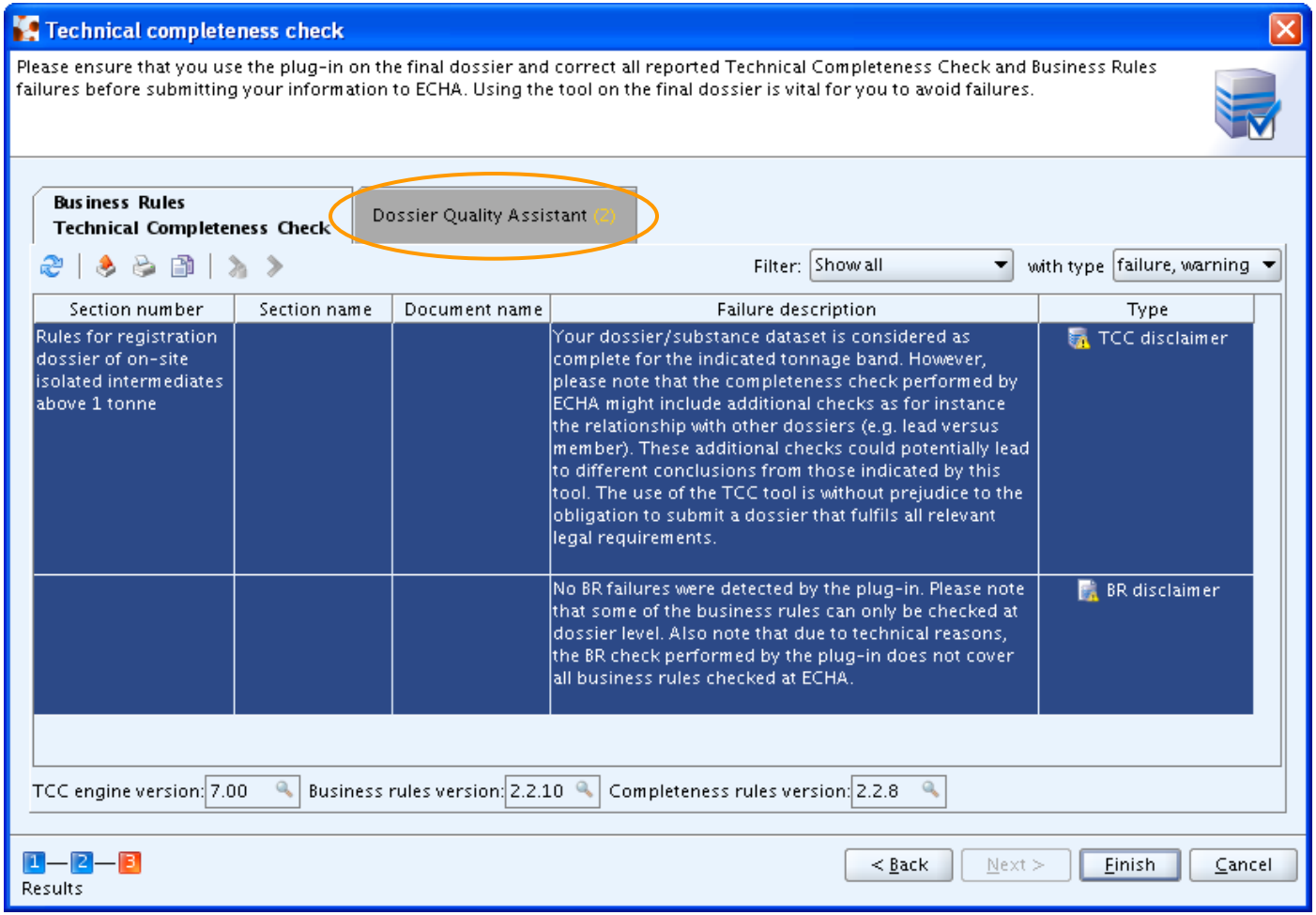
Be proactive – Dossier Quality Assistant

- ECHA evaluation work and screening activities have revealed inconsistencies in information provided;
- Frequent shortcomings collected in 'Dossier Quality Assistant' tool, a new feature in the TCC plugin 5.4.3 for IUCLID;
- Not a mandatory tool for the 2013 registration deadline; no impact on the outcome of the TCC;
- The Dossier Quality Assistant gives registrants visibility of ECHA's work to improve dossier quality;
- First version focuses on tonnage information, substance identity, intermediates, administrative part of study reports;
- The tool will be updated over time, incorporating more results from dossier verification activities.

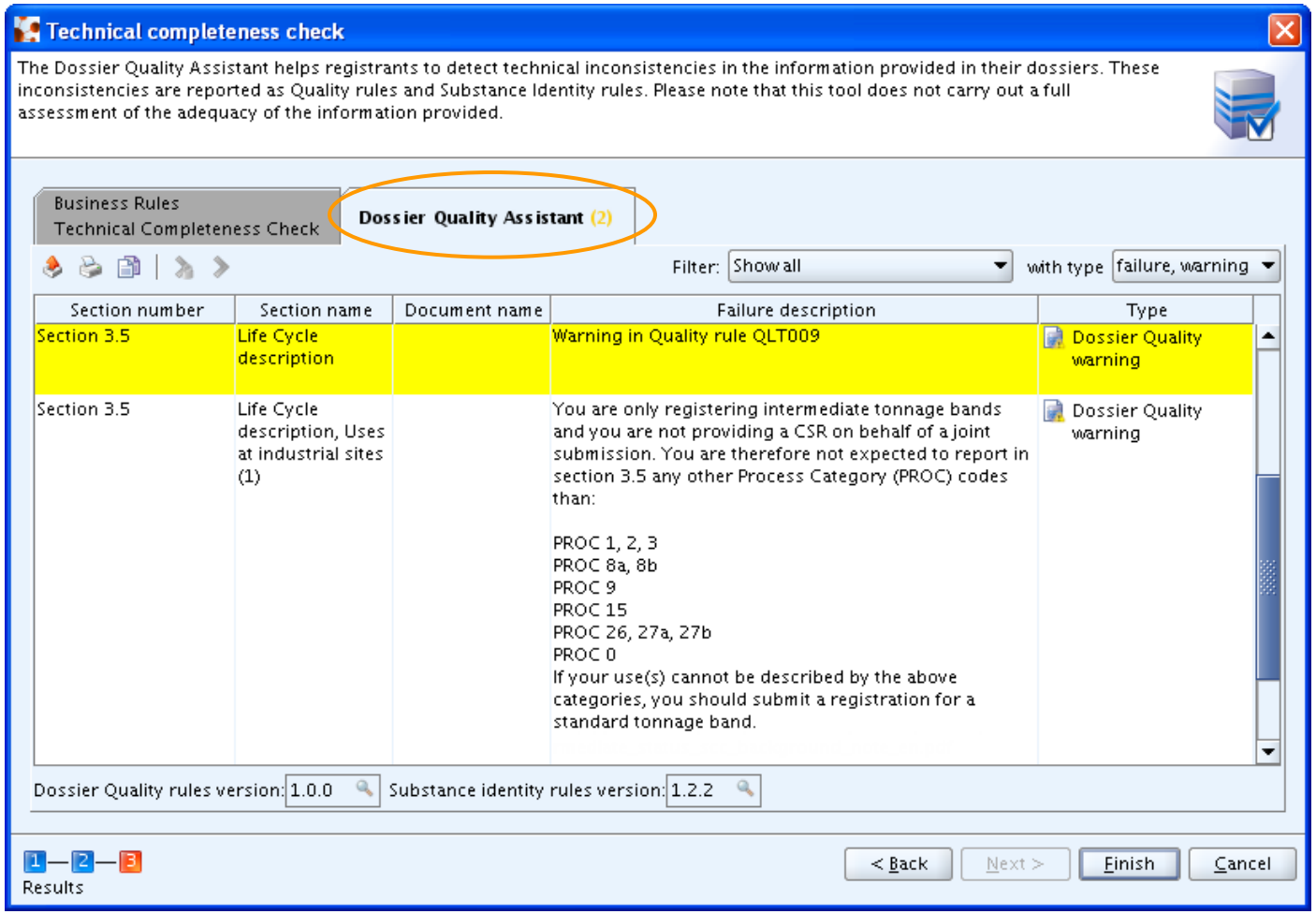
Dossier Quality Assistant



Dossier Quality Assistant



Dossier Quality Assistant



Be proactive…

- Read the Evaluation reports reflecting the dossier quality findings;
- Use the Dossier Quality Assistant;
- Analyse your situation and act for:
  - dossiers you prepare;
  - dossiers already submitted.
- Ensure resources and capacity to improve your dossiers and to keep your dossiers up to date.

… or be ready to react

Useful links

Dossier Quality Assistant Tool:

http://echa.europa.eu/view-article/-/journal_content/title/new-tool-to-support-registrants-in-improving-dossier-quality-now-available

http://iuclid.echa.europa.eu/

Article 54 report:

http://echa.europa.eu/view-article/-/journal_content/title/reach-evaluation-report-2012-quality-information-required-for-reach-compliance

http://echa.europa.eu/documents/10162/13628/evaluation_report_2012_en.pdf

Article 117.3 report:

http://echa.europa.eu/view-article/-/journal_content/57819962-e6bf-42a9-be76-cb172e0b5ccd

http://echa.europa.eu/documents/10162/13639/alternatives_test_animals_2011_en.pdf

Thank you