

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

Eighth Stakeholders' Day

26 March 2013

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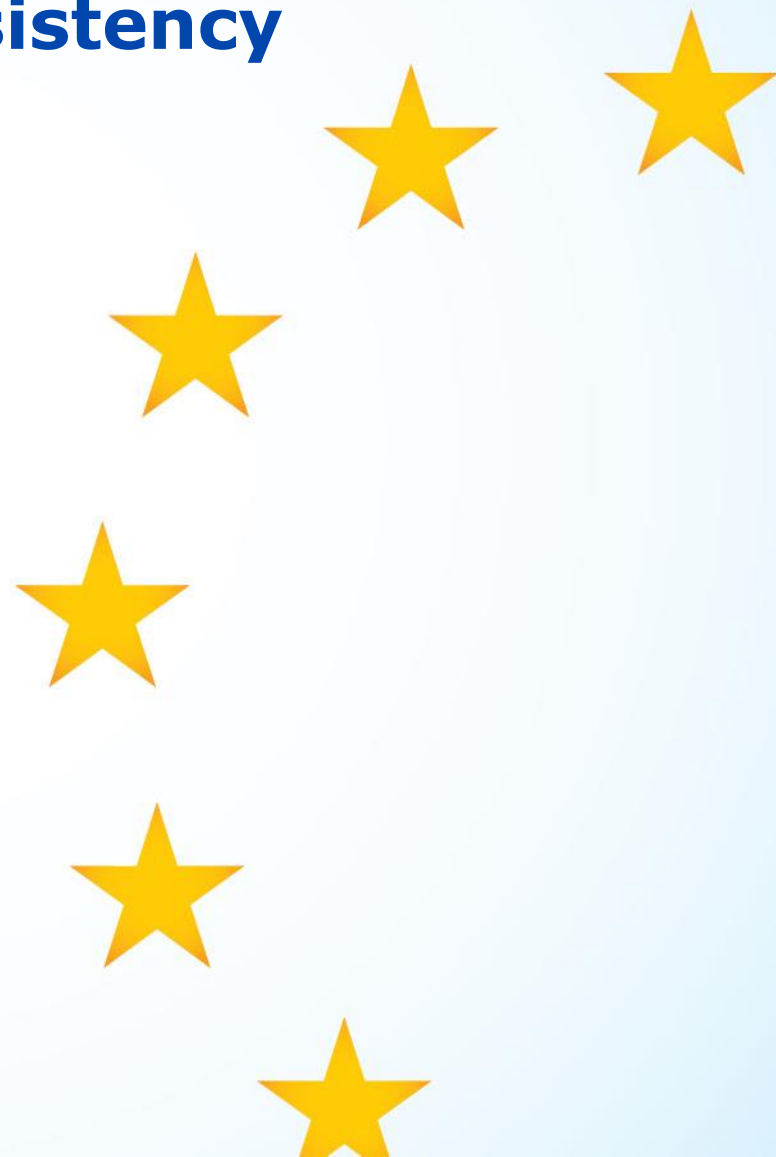
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Dossier quality and consistency

- **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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- 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.

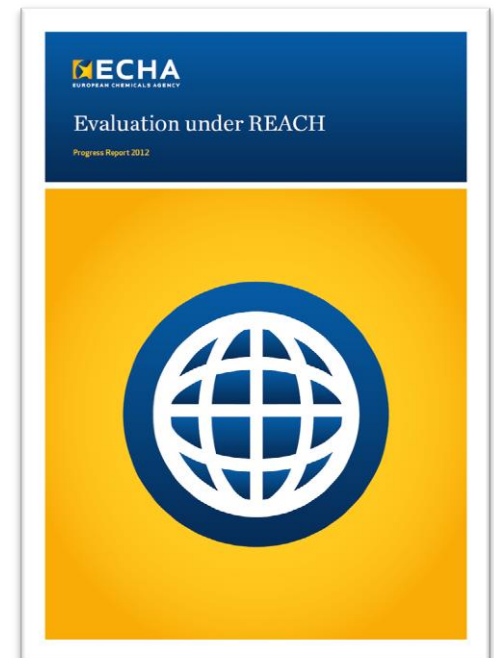
Dossier quality and consistency

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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.



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

Technical completeness check

Please ensure that you use the plug-in on the final dossier and correct all reported Technical Completeness Check and Business Rules failures before submitting your information to ECHA. Using the tool on the final dossier is vital for you to avoid failures.

Business Rules
Technical Completeness Check Dossier Quality Assistant (2)

Filter: Show all with type failure, warning

Section number	Section name	Document name	Failure description	Type
Rules for registration dossier of on-site isolated intermediates above 1 tonne			Your dossier/substance dataset is considered as complete for the indicated tonnage band. However, please note that the completeness check performed by ECHA might include additional checks as for instance the relationship with other dossiers (e.g. lead versus member). These additional checks could potentially lead to different conclusions from those indicated by this tool. The use of the TCC tool is without prejudice to the obligation to submit a dossier that fulfils all relevant legal requirements.	TCC disclaimer
			No BR failures were detected by the plug-in. Please note that some of the business rules can only be checked at dossier level. Also note that due to technical reasons, the BR check performed by the plug-in does not cover all business rules checked at ECHA.	BR disclaimer

TCC engine version: 7.00 Business rules version: 2.2.10 Completeness rules version: 2.2.8

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Results

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Dossier Quality Assistant

Technical completeness check

The Dossier Quality Assistant helps registrants to detect technical inconsistencies in the information provided in their dossiers. These inconsistencies are reported as Quality rules and Substance Identity rules. Please note that this tool does not carry out a full assessment of the adequacy of the information provided.

Business Rules
Technical Completeness Check

Dossier Quality Assistant (2)

Filter: Show all with type failure, warning

Section number	Section name	Document name	Failure description	Type
Section 3.5	Life Cycle description		Warning in Quality rule QLT009	Dossier Quality warning
Section 3.5	Life Cycle description, Uses at industrial sites (1)		<p>You are only registering intermediate tonnage bands and you are not providing a CSR on behalf of a joint submission. You are therefore not expected to report in section 3.5 any other Process Category (PROC) codes than:</p> <p>PROC 1, 2, 3 PROC 8a, 8b PROC 9 PROC 15 PROC 26, 27a, 27b PROC 0</p> <p>If your use(s) cannot be described by the above categories, you should submit a registration for a standard tonnage band.</p>	Dossier Quality warning

Dossier Quality rules version: 1.0.0 Substance identity rules version: 1.2.2

1—2—3
Results

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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

