How to bring your registration dossier in compliance with REACH – Tips and Hints Part 4

Conclusions

Rupert Simon

11 September 2013
11:00 - 13:00 Helsinki Time (EEST, GMT +3)

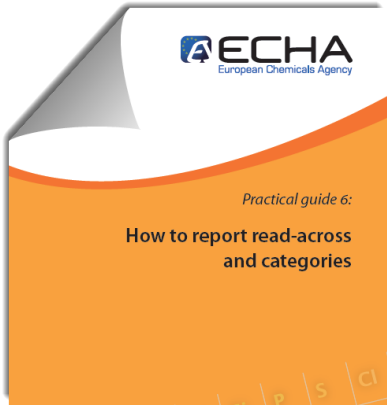
Details to remember - 1

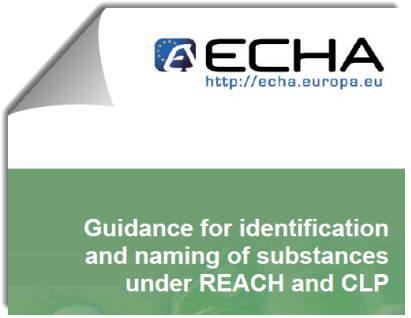
- Weight of Evidence:
  Report every independent piece of evidence separately as "endpoint study report" (ESR)
- Adaptations:
  Indicate the precise reference of the legal background (e.g.: Annex VII 7.3. column 2)
- Report quantitative results as numeric values
- Document the method used (test conditions, validity, QMRF, QMPF, etc.)

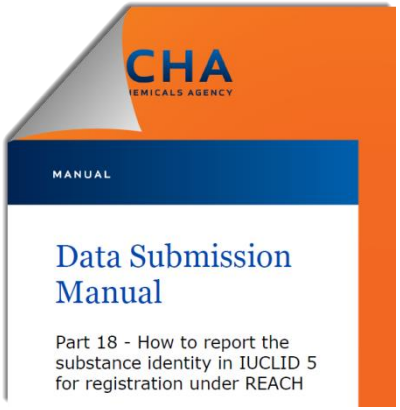
Details to remember - 2

- Report the constituents of the test material used to demonstrate the relevance of the study for your substance
- Document the validity of the study (i.e. that the validity criteria of the test method are met)
- It is always better to report more details, especially when the result of a study is used as adaptation argument to the standard testing regime (e.g. Column 2 adaptation "no testing needed, if …")

Information on the ECHA website







Information material

Evaluation progress reports
http://echa.europa.eu/regulations/reach/evaluation

Targeted Compliance check
http://www.echa.europa.eu/view-article/-/journal_content/1a87ce8e-6286-4d1b-9dc2-b2d10d6f1d79

Guidance document on Endpoint specific guidance (R.7)
http://echa.europa.eu/web/guest/guidance-documents/guidance-on-information-requirements-and-chemical-safety-assessment

Guidance document on QSARs and grouping (R.6)
http://echa.europa.eu/documents/10162/13632/information_requirements_r6_en.pdf

Practical guides 1, 2, 3, 4, 5 and 6
http://echa.europa.eu/web/guest/practical-guides

Tool to support improving dossier quality:

Plugin:

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

Upcoming webinars

Downstream users: Navigating ECHA's website for information on chemical substances
19 September 2013

Part 5 – How to bring your registration dossier in compliance with REACH – Tips and Hints
27 November 2013

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

Questions and Answers

- Questions will still be answered through the Q&A panel
  - You can continue to submit questions until 13:00h
  - Panelists will continue to answer your questions until 14:00h Helsinki time (UTC +2) via the Q&A panel (first come, first served)
  - The event will close at 14:00h Helsinki time (UTC +2)
  - If by then no answer is provided to your question, please send your question to the ECHA Helpdesk using the contact form: http://echa.europa.eu/en/web/guest/contact

- If you use the ECHA contact form:
  - You will receive an acknowledgement of receipt
  - Answer within 15 working days

Post event survey

- Once the event has ended, you will be directed to a post-event survey page
- Your feedback is important to us
- Your feedback helps us make the content of future webinars more relevant for your individual needs
- Please take the time to fill out the survey

Thank you!

http://echa.europa.eu/contact/helpdesk-contact-form