# How to bring your registration dossier in compliance with REACH

## Tips and Hints - Part 5

### Conclusions

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12 February 2014
11:00 - 13:00 Helsinki Time (UTC +2)

# Details to remember - 1

- Weight of Evidence:
  Report every independent piece of evidence separately as “endpoint study record” (ESR)
- Degradation simulation:
  Note that 12°C is the default temperature
- PBT and vPvB assessment
  Properties of degradation products required
- Wherever justifications are required, factual supporting evidence is needed in form of an ESR
- Specify legal basis for the adaptation
  (added after webinar)

# Details to remember - 2

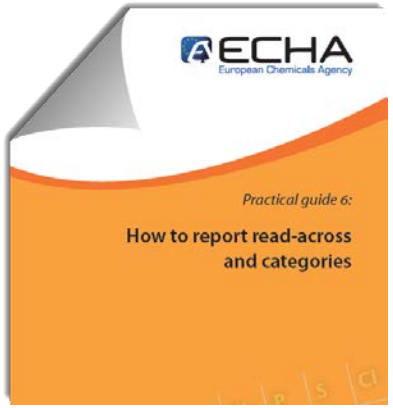
- Exposure based adaptations:
  Annex XI conditions are to be met, i.e. exposure and risk assessments are required

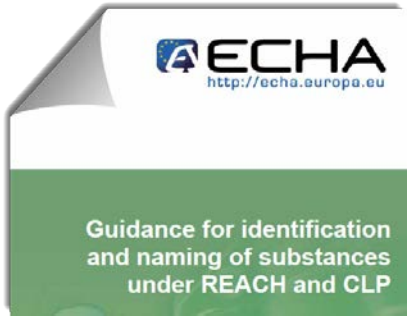
- Read across:
  Record the constituents of the source and target substances to demonstrate the relationship

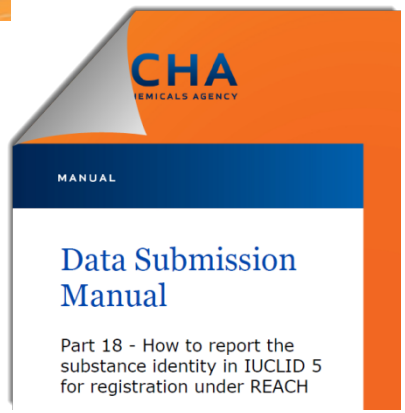
  - A detailed description of source and target substances is needed to have adequate justification for fulfilling the criteria for the read-across adaptation.

  - The need to demonstrate the relevance of the study for the substance registered applies generally to all cases (added after the webinar)

# 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, 6, 12 and 14
http://echa.europa.eu/web/guest/practical-guides

# Tool to support improving dossier quality:


Dossier Quality Assistant 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 6 – How to bring your registration dossier in compliance with REACH – Tips and Hints
Q4 2014

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 13:20h
  - 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

# Questions?

To the Q&A panel (between 11:00 and 13:30, Helsinki time), or

To the ECHA helpdesk (any time): http://echa.europa.eu/contact/helpdesk-contact-form