How to bring your registration dossier in compliance with REACH – Tips and Hints Part 2

Conclusions

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ECHA

28 January, 2013
11:00 - 14:00 Helsinki Time (GMT +2)

Questions and answers

- Submit your question
  - via the Q&A panel (until 13:00h Helsinki time, UTC +2)
  - via the ECHA helpdesk form (any time)

- If you submitted a question via the Q&A panel
  - monitor the Q&A panel for our response
  - remain logged-in to the Webinar
  - we answer until 14:00h (one hour after the last presentation)
  - After that: submit via the Helpdesk form

Use the correct format in IUCLID

Report any information as individual "endpoint study report" (ESR):

- Report adaptation arguments to the testing regime separate from experimental or in silico results (i.e. different ESR)
- Report underpinning data in a proper ESR (e.g. hydrolytical instability)
- Each adaptation to the standard testing regime needs to be reported in an ESR separately

Use the correct format in IUCLID

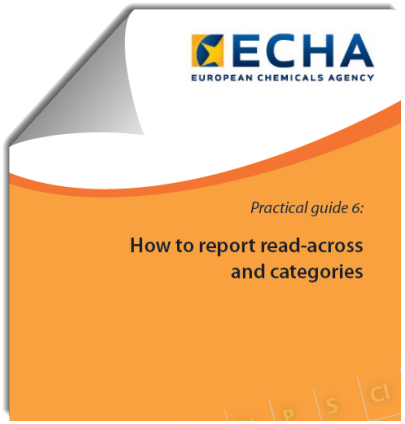
Transparency:

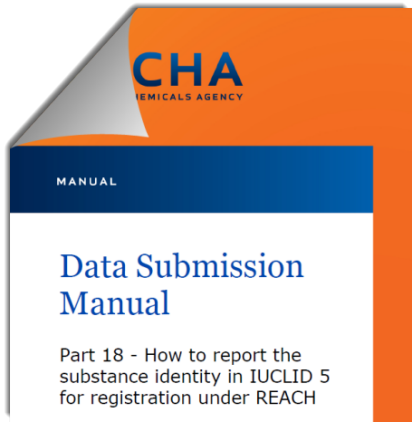
- Any information (old non-guideline data, weight of evidence, QSAR, etc.) need to cover the endpoint as the standard study would
- Report underpinning data for adaptations properly to avoid domino effect
- e.g. the hydrolysis endpoint must be fully covered if used for adaptation
- Absence of evidence ≠ evidence of absence

Improve your dossier quality now!

- Avoid common pitfalls
- Keep yourself up-to-date:
  - Evaluation progress reports
  - Follow our events
- Keep your dossiers up-to-date
  - Don’t wait for an ECHA decision

Information on the ECHA website





Information material

- Evaluation progress reports
  http://echa.europa.eu/regulations/reach/evaluation
- Targeted Compliance check
  http://echa.europa.eu/view-article/-/journal_content/1a87ce8e-6286-4d1b-9dc2-b2d10d6f1d79
- Guidance document on Endpoint specific guidance (R.7)
  http://echa.europa.eu/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/practical-guides

Upcoming events: Webinars

For lead registrants

- Last minute webinar on submission
  25 February 2013

For member registrants

- How to prepare and submit the member dossier
  5 March 2013

For all registrants

- Overview of the C&L platform
  19 March 2013
- How and when downstream users need to report to ECHA
  8 April 2013
- Part 3 – How to bring your registration dossier in compliance with REACH – Tips and Hints
  16 April 2013

Upcoming events: Conferences

- **Eighth Stakeholders' Day, 26 March 2013**
  The Agency's Eighth Stakeholders' Day conference focuses on providing support for member registrants. The conference is free of charge and registration is now open!
- **Biocides Stakeholders' Day, 25 June 2013**
  In preparation for the application date of the Biocidal Products Regulation the event aims to engage key biocides stakeholders with information about the new regulation.

Stay tuned to all the latest updates about ECHA events by subscribing to our e-News from the ECHA website!

Questions and Answers

- Questions will still be answered through the Q&A panel
  - Panelists will continue to answer your questions until 14:00 Helsinki time (UTC +2) via the Q&A panel (first come, first served)
  - The event will close at 14:00 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

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Thank you