

Key messages and closing

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

Part 1

27 September 2012

ECHA

Key messages

- Joint registration is not an option, it is a legal obligation
- Keep your dossiers up-to-date
- Keep yourself up-to-date with Evaluation Progress Reports and act to avoid common pitfalls
- Do not wait for a draft decision – **improve your dossier quality now!**
- Join or follow our events

General information

- Evaluation progress report 2011

http://echa.europa.eu/documents/10162/13560/mb_06_2012_general_report_2011_final_en.pdf

- Data submission manual 5

http://echa.europa.eu/documents/10162/13653/dsm5_tech_dossier_en.pdf

- FAQs about REACH section 6 and 11

<http://echa.europa.eu/web/guest/support/faqs/frequently-asked-questions/frequently-asked-questions-about-reach>

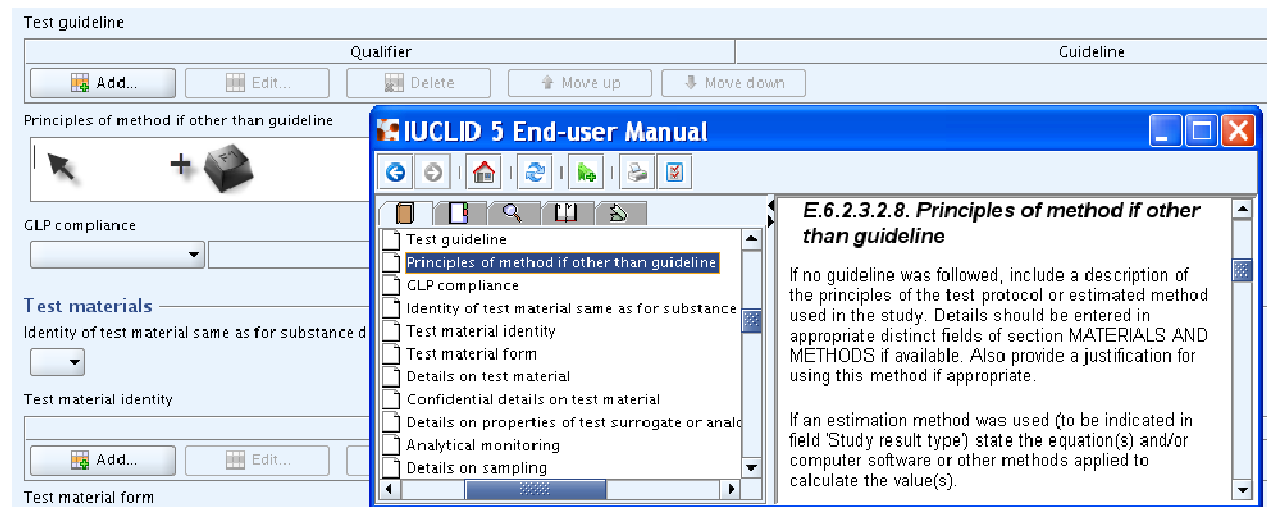
- **Targeted Compliance check**

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

- IUCLID end user manual

This manual is integrated in IUCLID software. →

To obtain this information, place your cursor in a specific IUCLID field and press F1 on your keyboard.



The screenshot shows the IUCLID software interface for entering test guideline information. The main window is titled 'Test guideline' and contains several sections: 'Principles of method if other than guideline', 'GLP compliance', 'Test materials', 'Test material identity', and 'Test material form'. Each section has an 'Add...' button. Overlaid on this is the 'IUCLID 5 End-user Manual' window, which is open to the section 'E.6.2.3.2.8. Principles of method if other than guideline'. The manual text reads: 'If no guideline was followed, include a description of the principles of the test protocol or estimated method used in the study. Details should be entered in appropriate distinct fields of section MATERIALS AND METHODS if available. Also provide a justification for using this method if appropriate. If an estimation method was used (to be indicated in field 'Study result type') state the equation(s) and/or computer software or other methods applied to calculate the value(s).'

Substance identification

- Guidance Document for Substance Identification

http://echa.europa.eu/documents/10162/13643/substance_id_en.pdf

- Data Submission Manual 18

http://echa.europa.eu/documents/10162/13653/substance_id_report_iuclid_en.pdf

Endpoints

- Guidance document on Endpoint specific guidance (R.7)

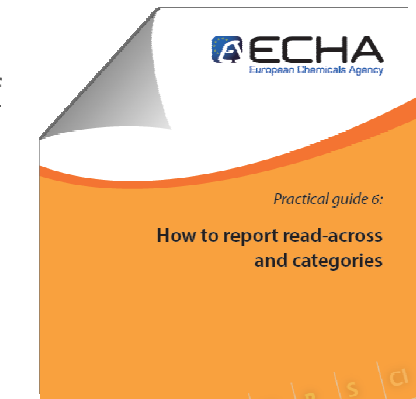
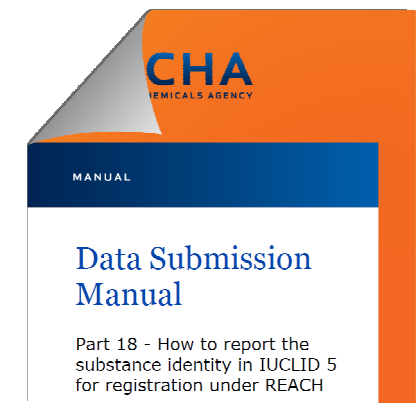
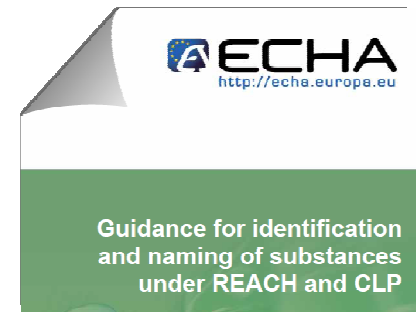
<http://echa.europa.eu/web/guest/guidance-documents/guidance-on-information-requirements-and-chemical-safety-assessment>

- 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>



Chemical Safety assessment

- Chesar 2 user manuals

<http://chesar.echa.europa.eu/web/chesar/support/manuals-tutorials>

- Illustrative Chemical Safety Report

http://echa.europa.eu/documents/10162/13634/csr_illustrative+example_en.pdf

- Practical guide 14

http://echa.europa.eu/documents/10162/13655/pg_14_on_hazard_endpoint_en.pdf

- Guidance document on Use descriptor system (R.12)

http://echa.europa.eu/documents/10162/13632/information_requirements_r12_en.pdf

- Guidance document on Hazard assessment (Chapter B.8)

http://echa.europa.eu/documents/10162/13643/information_requirements_part_b_en.pdf

Chesar 2
User manual

**Part 4 - Exposure scenario
building and CSR generation**



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**How to prepare toxicological summaries in
IUCLID and how to derive DNELs**
Practical Guide 14

Part B: Hazard Assessment

B.8 SCOPE OF EXPOSURE ASSESSMENT

B.8.1 Background and aim of the chapter

Article 14(1) and (1) of REACH require that exposure assessment and subsequent risk characterisation be carried out for substances subject to regulation, which are manufactured or imported in a quantity equal to or greater than 10 tonnes/year, and where the relevant conditions in the hazard assessment that the substance fulfils the criteria for classification in any of the hazard classes or categories listed in Article 4(1) of Regulation (EC) No 1272/2008 (CLP Regulation), amending Article 14(4) of the CLP Regulation from 1 December 2010, namely:

- hazard classes 2.1 to 2.4, 2.6 and 2.7, 2.8, (Class A and B, 2.9, 2.10, 2.12, 2.15, categories 1 and 2, 2.14, categories 1 and 2, 2.15 type A to F,
- hazard classes 3.1 to 3.6, 3.7 adverse effects on sexual function and fertility or on development, 3.8 effects other than narcotic effects, 3.9 and 3.10,
- hazard class 4.1,
- hazard class 5.1,
- or PBT, vPvP properties.

These classes, categories and properties will henceforth be referred to as "hazard classes, categories or properties".

On the basis of it is decided that exposure and risk characterisation is the next step is to decide the scope of the exposure assessment. Accordingly, exposure assessment has to cover all hazards that have been identified in Article 1 of REACH. For the sake of clarity it should be noted that the necessary exposure assessment are of three types:

- hazards for which there are classification criteria and thus to which the substance meets the criteria and is therefore classified;

Upcoming events

Lead Registrant Webinars

- **General Principles of Dossier Preparation & Submission**
19 October 2012
- **Registration process I: Business Rules**
9 November 2012
- **Registration process II: Technical Completeness Check, Invoicing and payment**
22 November 2012

Webinars open for all

- **What should every registrant know about Substance Evaluation?**
5 October 2012
- **Part 2 – How to bring your registration dossier in compliance with REACH – Tips and Hints**
December 2012

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

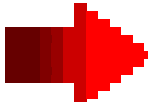

Upcoming events

Workshops and Events

- **Lead Registrant Workshop 11 to 12 October 2012**
The Agency's second workshop for lead registrants continues to provide support and networking opportunities ahead of the 2013 deadline.
- **8th Stakeholders' Day, March 2013**
The Agency's Eighth Stakeholders' Day conference focuses on providing support for member registrants. Further information will be available on ECHA's website soon.

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 on a first come, first served basis until 17:30 EEST (GMT+3) via the Q&A panel
 - Note that **the event will automatically close** at 17:30 EEST (GMT +3)
 - **If no answer is provided** to your question by the closing of the webinar, we ask you to send your question to the ECHA Helpdesk:
 - ECHA website  Support  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
very much for your
attention**

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